

**CONTINUING CARE THROUGH TELE-COUNSELLING IN ALCOHOL DE-
ADDICTION PROGRAM – A RANDOMIZED CONTROLLED STUDY**

Submitted

BY

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Dissertation submitted to

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In partial fulfilment of the requirements for the degree of

DOCTOR OF MEDICINE IN PSYCHIATRY

2014

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled “**Continuing care through tele-counselling in alcohol de-addiction program – A randomized controlled study**” is a bonafide and genuine research work carried by me under the guidance of Dr. G.Raghuthaman, Prof and Head, Department of Psychiatry, PSGIMS & R, Coimbatore.

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At the outset, I thank God for giving me the strength to perform all my duties.

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November 22, 2012

To
Dr R R Pranesh
1 Year Post Graduate
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Ref.: Study titled: Continuing care through tele-counselling in alcohol de-addiction program
- A randomized controlled study

Sub.: Ethics Committee Approval for the study

The Institutional Human Ethics Committee, PSG IMS & R, Coimbatore -4, has reviewed your proposal on 26th October, 2012 in its full board review meeting held at College Council Room, PSG IMS&R, between 2.00 pm and 5.00 pm, and discussed your application to conduct the study entitled:

"Continuing care through tele-counselling in alcohol de-addiction program - A randomized controlled study"

The following documents were received for review:

1. Duly filled application form
2. Informed Consent forms in English and Tamil
3. Data Collection Tool
4. CV

The members who attended the meeting at which your study proposal was discussed are as follows:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
2	Mrs. R. Geetha	+ 2	Lay person	Female	No	Yes
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6	Dr. G. Rajendiran	DM	Clinician (Cardiology)	Male	Yes	Yes
7	Dr. V. Ramamurthy	Ph D	Biotechnology	Male	Yes	Yes
8	Dr. M. Ramanathan	M Pharm, Ph D	Non-Medical (Pharmacy)	Male	Yes	Yes

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10	Dr. Seetha Panicker	MD	Clinician (Obstetrics & Gynaecology)	Female	Yes	Yes
11	Dr. S. Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
12	Dr. Y.S. Sivan	Ph D	Social Scientist (Sociology)	Male	Yes	Yes
13	Dr. Sudha Ramalingam (Alternate Member-Secretary, IHEC)	MD	Public Health, Epidemiology, Genetics, Ethicist	Female	Yes	Yes
14	Mrs. K. Uma Maheswari	M Sc, M Phil B Ed	Botany	Female	No	Yes
15	Dr. D. Vijaya	M Sc, Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

After due consideration, the committee has decided to approve the above proposal.

The approval is valid for one year.

We request you to intimate the date of initiation of the study to IHEC, PSG IMS&R.

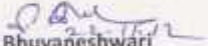
We hereby confirm that neither you nor any of your study team members have participated in the voting/ decision making procedure of the committee. The members of the committee who have participated in the voting/ decision making procedure of the committee do not have any conflict of interest in the referenced study.

This Ethics Committee is organized and operates according to Good Clinical Practice and Schedule Y requirements.

Non-adherence to the Standard Operating Procedures (SOP) of the Institutional Human Ethics Committee (IHEC) and national and international ethical guidelines shall result in withdrawal of approval (suspension or termination of the study). SOP will be revised from time to time and revisions are applicable prospectively to ongoing studies approved prior to such revisions.

PIs are required to send progress reports (in the form of an extended abstract with publications if any) to the IHEC every six months (and a month before expiry of approval date, if renewal of approval is being sought).

Request for renewal must be made at least a month ahead of the expiry of validity along with a copy of the progress report.


Dr S Bhuvaneshwari
Member - Secretary
Institutional Human Ethics Committee



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ABSTRACT

Continuing Care Through Tele-Counselling in Alcohol De-Addiction

Program – A Randomized Controlled Study

INTRODUCTION

There is a rising trend of alcohol addiction in our Indian society. Promised by the effectiveness of western studies in using telephone based counselling services and the availability of extensive mobile phone services in our part, we did this novel study, first of this kind in India

Type of the study: **Prospective randomized controlled study**

METHODOLOGY:

We recruited admitted in-patients qualified for alcohol dependence and randomized them at the time of discharge into two groups: 1) ‘Telephone Continuing Care ’ group (TCC) who received pro-active contact and counselling through mobile phones from the treatment team at 1st, 2nd, 4th, 8th, 12th, 16th, 20th and 24th week after discharge. 2) ‘Treatment-As-Usual’ group (TAU) received usual out-patient follow-up care. We contacted patients and their care-givers, belonging to both groups, each month over mobile phone and collected information regarding drinking status. We compared abstinence rates,

drinking percentage days and treatment adherence rates. By including all the variables, we did logistic regression to predict relapse.

RESULTS

There was no statistical significance between two groups in terms of abstinence rate (TCC: 66.7% and TAU: 55.6%); however among the group from whom complete data was obtained abstinence rate was slightly better in TCC group (TCC: 67.9% and TAU: 43.8%, $p=0.06$). There was no difference in the drinking percentage days. TCC group was significantly better than TAU group in having longer duration of follow-up, good drug compliance, adherence to group meetings and lower dropout rate. Logistic regression revealed that family history of alcoholism, three weeks admission for de-addiction, drug compliance and length of follow-up were found to be significant predictors of relapse.

CONCLUSION

Telephone continuing care showed few positive findings in improving the outcome and this could be included in the armamentarium of de-addiction program.

Key words: tele-counselling, alcohol deaddiction, outcome.

INTRODUCTION:

Alcohol dependence is a chronic condition with multiple relapses. According to WHO statistics, in 2010-11, there were nearly 1.8 million alcohol related deaths which is 3.2% of total deaths in that year. In India alone, there were 62.5 million alcohol users with 17.4% of them (10.6 million) fulfilling criteria for dependence [1, 2].

Treatment of alcohol addiction is a challenging task, requiring a multistep approach for sustaining recovery from addiction. Treatment focussing mainly on ‘acute crisis management’ of alcohol dependence failed to give sustained recovery due to higher relapse rates [3, 4, and 5]. Many outcome studies[6,7,8,9] proved extended continuing care in managing alcohol addiction to be effective. This continuing care is comparable to the care in managing chronic mental illness such as Depression[10,11], Obsessive Compulsive Disorders[12,13] and as well as in chronic physical diseases such as Hypertension, Diabetes and Rheumatology problems[14,15,16].

Dropout rate was high in case of ‘face-to-face interview type’ continuing care [17, 18, and 19]. This could be because of stigma attached to visiting mental health centres [20, 21, and 22] shortage of manpower, inadequate infrastructure and long distance with difficult transportation facilities. So, there is a need for an alternative to the usual ‘face-to-face interview type’ of continuing care. Telephone based follow up care offers a more feasible form of taking care of patients’ inconveniences [23, 24].

American Society of Addiction Medicine 2001[25] and McKay 2005[26] clearly reported about effectiveness of both ‘face to face interview’ and ‘telephone based’ continuing care in treating substance use disorders. Other studies focussing on continuing care through telephone also proved benefits in controlling alcohol addiction [3,24,27,28,29] , other substance use disorders[30,31] and smoking [32,33].

All the above studies were done in western countries and there is no published research in India, where the need of telephone based continuing care is large.

According to the report of Ministry of Telecommunications [34], India has 9435.03 lakhs of telephone connections (Urban - 6187.72 lakhs and Rural - 3247.31 lakhs). Currently, our tele-density stands at 78.10% and it has been increasing by 12.7% every year. With more than two-thirds of the population having access, telephone based follow-up care could be feasible and effective among patients.

There is a rising trend of alcohol addiction in our Indian society [35, 36] and the traditional de-addiction treatments had yielded abstinence rates of 12.3% [17], 32.5% [37] and 55% [38]. Such a low success rate is not acceptable and we have to look for alternative mode which improves treatment delivery and success rate.

RATIONALE OF THE STUDY:

Promised by the effectiveness of western studies in using telephone based counselling services and the availability of extensive mobile phone services in our part, we had planned this study.

Among patients who received in-patient treatment for alcohol dependence syndrome, we compared the effectiveness of abstinence rates and compliance rates between ‘treatment as usual’ follow-up patients and ‘telephone continuing care ’ group who had received pro-active contact and counselling through mobile phones from the treatment team.

REVIEW OF LITERATURE:

Alcohol dependence and its effective management was always a tricky condition. Successful treatment depends on several factors. Search for effective tools in improving the outcome of treatment of alcohol addiction has always been a burning issue.

Telephone based interventions have been studied previously. Considering easy availability and cost effectiveness, studies have shown telephone based interventions to be helpful in improving the outcome results in common non-communicable disorders such as Diabetes and Hypertension [14, 15].

Similarly, to improve the outcome measures in the management of substance disorders, few studies have been carried out [4, 7]. Results in substance disorders such as nicotine, cocaine and sedatives were mixed. [29, 30]

Hubbard et al (2007) [30] carried out a study to find out the effectiveness of telephone based interventions in management of nicotine disorders. Study showed better outcomes in patients had received telephone based interventions in smoking cessation. Similarly, other outcome studies and meta-analytic review on substance disorders showed encouraging results in controlling substance disorders. [29, 32, 33]

There were many studies done in western countries to find out the ways of improving outcome measures in the management of alcohol addiction. [3, 6, 18] Continuing care through telephone based counselling forms the recent decade trend of improving management strategies for substance disorders.

Most of the studies were longitudinal prospective studies to find out effectiveness of tele-counselling in alcohol de-addiction programme. Very few were randomized controlled trials comparing telephone based continuing care and other modes of continuing care in treating alcohol dependence. [3, 6, 18]

In 2010, **Godley et al [6]** did their study in Illinois, United States. Their study included 104 subjects fulfilling criteria for alcohol dependence, who were admitted for residential treatment for alcohol de-addiction. They were randomized into two groups.

One group, **telephone based continuing care**, comprised of 51 patients who received proactive tele-counselling for first three months and the other group, **usual continuing care**, comprised of 53 subjects. Mean age of subjects was 31.6 years. They were followed up for 6 months period.

Telephone based care group received counselling sessions from the treating team once a week in the first month and then every fortnight over the next two months. In last three months, they were contacted once a month.

At the end of 6 months study, there was no significant difference in the abstinence rate between the two groups (87.39 % in telephone group vs. 84.64 % in usual treatment group). But in the lower severity group of alcohol dependent patients, there was a statistical significant difference in the abstinence rate at the end of 3 months, however this statistical significance was not seen at 6 months.

Similarly, there was no significant difference in outpatient session attendance and Substance Problem Scale between two groups. Although there was a trend towards significance at the end of three months (0.06), there was no major difference in outcome measures between two groups.

Mckay et al (2005) [3] conducted a longitudinal prospective study in Philadelphia, United States to find out the effectiveness of telephone based counselling in managing alcohol and cocaine disorders. The total sample was 359 subjects, of which 91 patients were having alcohol dependence alone and remaining 268 patients were having comorbid cocaine dependence.

The sample was divided into three groups. The first group received telephone based monitoring and brief counselling. The second group was relapse prevention group and the third one was standard 12 step group counselling group. Both relapse prevention group and standard 12 step group counselling group were face to face interventional groups.

They were followed up for 2 years and outcomes at the end of 1st year and 2nd year were published.

At the end of first year, the study did not find any superiority of telephone based monitoring group in outcome measures over face-face interventional groups.

At the end of 2 years, telephone based group had higher rates of total abstinence than standard 12 step counselling group ($p < 0.05$). Also 24 month gamma glutamyl transferase level in telephone group was lower compared to relapse prevention face-to-face group ($p = 0.05$). The results were more significant for alcohol outcome measures than for cocaine.

The above few studies done in western countries compared the effectiveness of telephone based care in treating alcohol disorders. In India, there has not been any published article regarding telephone continuing care in treating alcohol dependence. However, there are many outcome studies done in India to find out the effectiveness of alcohol deaddiction treatment and predictors of abstinence. [17, 37, 38]

Abraham et al (1997) [37] carried out a one year prospective study at JIPMER, Pondicherry. They recruited the patients admitted in the hospital for alcohol de-addiction treatment, which included detoxification, group sessions and disulfiram medications. Sixty patients were followed up for a year.

Mean age of the sample was 39.6 years (± 8.5). 81.6% of total subjects were married. 54.5 % had family history of alcoholism.

They were advised to come for follow-up every two weeks after discharge. Out of the 60 subjects, only 9 patients had follow-up in clinic at the end of a year. Thirty one patients had follow-up for less than 3 months and 10 patients were attending for period of 3-6 months. The remaining 10 patients missed follow up within 1 month.

At the end of one year, 32.5% patients remained abstinent; 35% of patients continued drinking but improved compared to previous drinking pattern and; 32.5% patients continued to have unimproved drinking pattern.

Chandrasekaran et al [17], 2001 did a retrospective study at JIPMER, Pondicherry to find out follow up rates of patients treated for alcohol addiction. They recruited 800 alcohol dependence patients treated over five years period.

Mean age of the subjects was 39.7 years (± 8.66). Recruited patients had moderate severity of alcohol dependence, indicated by their mean SADQ score was 23.95.

Out of 800 patients, only 28 patients (4.6%) were on regular follow up for 1 year; 48 patients (7.9%) were on regular follow for 6-12 months and; 152 patients (25.1%) were coming for follow up for less than 6 months period, but greater than a month.

There was a very high drop-out rate. Within one month 379 patients (62.4%) dropped out from treatment, which is significantly high compared to other contemporary Indian studies. [37, 38]

Kar et al [38], 2003 carried out one year prospective study in Kasturba Medical College, Manipal.

They recruited 60 patients who fulfilled the criteria for alcohol dependence and admitted for de-addiction treatment, which includes detoxification, psychoeducation, aversion therapy, group therapy and disulfiram medication.

Mean age of the sample was 42.86 years. Recruited patients had onset of regular drinking around 30.85 years. Around 92% of the recruited patients were prescribed disulfiram at the time of discharge. They were followed up for a year.

At the end of one year 28 patients (46.7%) were abstinent. Five patients (8.3%) were drinking occasionally and 21 patients were having >50% drinking days. Remaining 6 patients (10%) were drop outs.

Greater the average age of problem drinking, lower psychosocial problems and lack of family history of alcoholism were found to be predictors of abstinence in patients who had completed de-addiction treatment.

AIMS & OBJECTIVES:

Our aim was to assess the effectiveness of providing **continuing care through telephone** to patients who had received in-patient de-addiction treatment. We also aim to find out the risk factors that would predict relapse in the whole sample.

Our objectives are:

1. To prospectively study the abstinence rate between two groups: a) Telephone Continuing Care (TCC) and b) Treatment As Usual (TAU).
2. To study secondary outcome measures such as drinking frequency, length of abstinence ,drug compliance and length of follow-up in clinic in the above 2 groups.
3. To assess the rate of abstinence and relapse among patients for whom we got complete follow-up data for 6 months (Completers).
4. To study the factors that would predict relapse among Completers group.

METHODOLOGY

All patients admitted to the Department of Psychiatry with the clinical diagnosis of Alcohol Dependence Syndrome were administered SCID (Structured Clinical Interview for DSM disorders) and patients who qualified for the DSM IV TR diagnosis of Alcohol Dependence Syndrome were recruited for our study. We assessed the severity of dependence by using the Severity of Alcohol Dependence Questionnaire (SADQ). We assessed the motivational level of recruited patients using University of Rhode Island Change Assessment Scale (URICA).

SADQ is 20-item self administered questionnaire developed by Stockwell et al [39] for assessing the severity of alcohol dependence. We used SADQ –community version which measures the severity of alcohol dependence in last three months. It was measured in 0-3 point scale with a maximum score of 60. A score of greater than 30 was considered as severe alcohol dependence.

University of Rhode Island Change Assessment Scale (URICA) is a self administered motivational scale, measuring patients' readiness to change, originally developed by Di Clemente. There are 32-item, 24-item and 12-item

questionnaires. We used 12-item scale for the current study. The results were described in four stages : Precontemplation, Contemplation, Action and Maintenance. The items of SADQ and URICA were translated from English to Tamil and back translated to English by 2 independent persons. We used the Tamil version of SADQ and URICA on our patients.

After admission, all these patients were offered the standard treatments practised in the Department of Psychiatry. Initially all of them had detoxification treatment and majority of them underwent de-addiction treatment which include motivational interviews, Cue Analysis, Cue Management, Covert Sensitization, Aversion Therapy and Group Therapy. They were discharged with medications to maintain abstinence.

Patients who have phone connections either landline or mobile were only included in the study. Patients with co-morbid severe mental disorder and cognitive impairments were excluded from the study.

At the time of discharge from the hospital, we randomized the patients into 2 groups: 1) Telephone Continuing Care (**TCC**) and 2) Treatment As Usual (**TAU**).

Telephone Continuing Care (TCC):

We contacted patients belonging to this group at the following frequency: 1st, 2nd, 4th, 8th, 12th, 16th, 20th and 24th week after discharge. During such contacts, **five-minute proactive counselling** was provided on the following themes:

- a) Enquiring about abstinence and encouraging remaining so.
- b) Probing for ‘craving’ and practice of ‘relapse prevention strategies’.
- c) Discussing health hazards he had sustained due to alcohol.
- d) Ensuring compliance with medications.
- e) Encouraging attendance for group therapy.
- f) Advising to attend follow-up visits at the de-addiction clinic.

Patients belonging to this group also were getting the standard treatment at the hospital: attending de-addiction clinic, participation in group therapy and seeing their primary therapists.

Treatment As Usual (TAU):

Patients belonging to this group were receiving follow-up treatments from their respective primary therapists. They received psychological treatment and medications during their consultations. They were encouraged by their therapists to attend outpatient group therapy which occurs once a week.

Assessments:

We contacted **patients and their primary carers** belonging to both the groups at 4th, 8th, 12th, 16th, 20th, 24th week over mobile phone or telephone. During that time we conducted semi-structured interviews to get information regarding the drinking status of the patients. In case, patient had restarted drinking, we got the following information: number of drinking days in the previous 4 weeks and about number of drinks per day. The information obtained from the patients and their primary carers were recorded separately.

The primary outcomes were **Abstinence and Drinking percentage days**.

We analysed abstinence by dividing into 4 groups:

- 1) Abstinence: Patient had not touched alcohol
- 2) Occasional drinking: Patient had taken alcohol but not drinking every day
- 3) Daily drinking: Patient drinks alcohol every day but not during the day time
- 4) Daytime drinking: Drinking even during the day time.

We also calculated **Drinking percentage days** as:

Number of drinking days/Total days

Sample size estimation:

32.5% of patients remained abstinent and non-problem drinker at the end of one year after a routine de-addiction treatment (Abraham J, 1997) and we hypothesized that Telephone Continuing Care would improve the abstinent rate to 60%.

The required sample size to detect this difference in the abstinent rates between the 2 arms (keeping alpha as 0.05 and beta as 0.2), was 34 patients in each arm. Assuming dropout rate as 10%, we needed 38 patients in each arm.

ANALYSES:

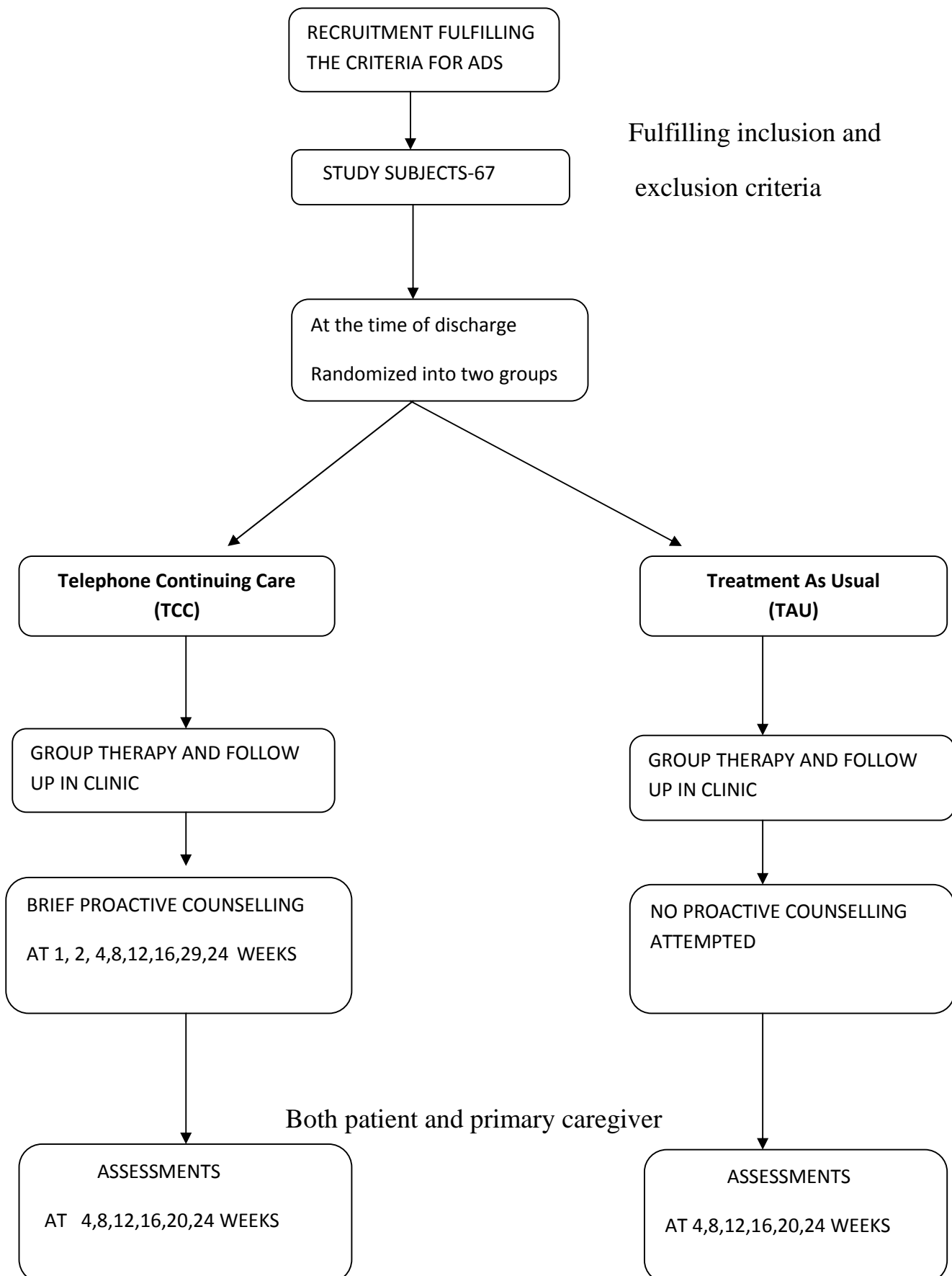
- Statistical analysis was conducted using SPSS version 19.0 for Windows.
- All variables were checked for normality using the Kolmogorov-Smirnov test. We did parametric tests for the normally distributed data and did non-parametric tests for the rest.
- We used student's t test to compare the following normally distributed continuous variables: Mean time for the first drink, mean drinking days percentage, duration of alcohol intake, duration of daily drinking, SADQ score,
- As the following continuous variables were not normally distributed we used Mann Whitney U test to compare the mean between the groups: onset of first drink, number of cigarettes smoked per day, abstinent episodes, length of abstinence, SCID score, URICA score, duration of hospital stay, length of follow-up, duration of drug compliance, group visits and
- Chi-square test and fisher's exact test were used to compare categorical variables: marital status, socio-economic status, telephone status, smoking status, other substance status, co-morbid medical illness, family history of alcoholism, history of withdrawal seizures, delirium tremens, benzodiazepine use, SADQ grade, URICA grade, de-addiction treatment

components, abstinence medications and primary outcome measures:

number of patients remaining abstinent and relapsed.

- In the whole sample, among patients who had complete data for 6 months, we did bivariate analyses to see whether there is any association between relapse and the following variables:
 - Socio-demographic factors, history of alcoholism in the family
 - Features of alcoholism (age of onset of first drink, age of onset of daily drinking of alcohol, duration of alcohol use, Severity of Alcohol Dependent Questionnaire score, no. of abstinent episodes, length of abstinent periods, history of withdrawal seizures, history of delirium tremens)
 - Level of motivation as assessed by URICA scale
 - Treatment factors (length of hospital stay for de-addiction, different components of de-addiction treatment, medications used to maintain abstinence, drug compliance and length of follow-up in the clinic).
- We did logistic regression by including all the above variables in the logistic model to see which variables would predict relapse. We did Omnibus tests of model coefficients to see the significance of our model and we did Hosmer and Lemeshow test whether our logistic model is a fit model.
- A significance level of $p < 0.05$ was used in the study.

FIG 1: FLOW CHART DESCRIBING THE METHODOLOGY:



RESULTS

1. Baseline profile of the study sample
2. Comparing primary and secondary outcome measures between Telephone Continuing Care (TCC) and Treatment As Usual (TAU) groups.
3. The rate of abstinence and relapse among patients for whom we got complete follow-up data for 6 months (Completers).
4. Among completers, predictors of relapse using bivariate analyses and logistic regression.

There were 77 patients admitted who fulfilled the criteria for alcohol dependence during study period. Out of 77 patients, 8 patients were excluded because of comorbid severe mental disorder and 2 patients were not willing to consent. Hence, remaining total of 67 patients who fulfilled the inclusion criteria were randomly assigned to **‘Telephone Continuing Care (TCC)’** and **‘Treatment As Usual (TAU)’** groups.

There were 34 patients in the TCC group and 33 patients in the TAU group. We were able to follow-up and obtain data for 60 patients for the entire 6 months and 7 patients dropped out during the course of the study (TCC=1 and TAU=6).

1. BASELINE PROFILE OF STUDY SAMPLE:

All patients were males and their mean age was 41.10 years and 91 % of them were married. Both the groups were comparable in all the sociodemographic variables as shown in below Table. No 1

TABLE 1: BASELINE SOCIO DEMOGRAPHIC DETAILS OF THE STUDY**SAMPLE**

VARIABLES	TOTAL SAMPLE N=67	Telephone Continuing Care (TCC) N=34(%)	Treatment As Usual (TAU) N=33(%)	Statistics
<u>Age</u> Mean (S.D)	41.10 yrs (8.63)	40.76 yrs(7.64)	41.42 yrs(9.65)	t=0.29,df=65,p=0.77
<u>Marital status</u> n (%)				
Married	61(91)	32(94.1)	29(87.9)	
Unmarried	5(7.5)	2(5.9)	3(9.1)	2=1.33,df=2,p=0.514
Separated	1(1.5)	0	1(3)	
<u>Socio economic status</u>				
Upper (%)	1(1.5)	-	1(3.03)	
Upper middle(%)	20(29.9)	9(26.5)	11(33.3)	2=0.98,df=3,p=0.764
Lower middle(%)	23(34.3)	13(38.2)	10(30.3)	
Lower(%)	23(34.3)	14(41.2)	11(33.3)	
<u>Telephone status of caregiver</u> n(%)				
Present	46(68.7)	23(67.6)	23(69.7)	
Absent	21(31.3)	11(32.4)	10(30.3)	2=0.33,df=1,p=0.856

TABLE 2: BASELINE CLINICAL CHARACTERISTICS OF THE STUDY SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
<u>Smoking status</u> <u>(%)</u>				
Present	43(64.2)	19(55.9)	24(72.7)	2=2.067,df=1,p=0.15
Absent	24(35.8)	15(44.1)	9(27.3)	
No of cigarettes	9.82(12.08)	9.76(12.76)	9.88(11.54)	U=510,z=-.65,p=0.51
<u>Other substance</u> <u>use n (%)</u>				
Present	14(20.9)	3(8.8)	11(33.3)	2=6.08,df=1,p=0.014
Absent	53(79.1)	31(91.2)	22(66.7)0	
<u>Medical illness</u> <u>n (%)</u>				
Present	24(35.8)	10(29.4)	14(42.4)	2=1.23,df=1,p=0.267
Absent	43(64.2)	24(70.6)	19(57.6)	
<u>Family history</u> <u>Of alcoholism</u> <u>n(%)</u>				
Present	52(77.6)	28(82.4)	24(72.7)	2=0.893,df=1,p=0.345
Absent	15(22.4)	6(17.6)	19(27.3)	

In the total sample, 64.2% of patients were smokers and 20.9% were using substances like tobacco chewing, cannabis, benzodiazepines and these patients were equally represented in TCC and TAU groups. A high number of patients (77.6%) had positive family history of alcoholism.

BASELINE ALCOHOL PROFILE OF STUDY SAMPLE

ONSET OF FIRST DRINK:

Mean onset of first drink of total subjects was 20.82 years. There was no statistical significance between two groups as shown in Table.3

ONSET OF DAILY DRINKING:

Mean age of onset of daily drinking in our sample was 30.52 years. Telephone continuing care group was having slightly earlier onset of daily drinking compared to other group but not statistically significant as shown below in the Table.3

DURATION OF ALCOHOL INTAKE:

Average duration of alcohol intake of total subjects was 20.25 years. Alcohol intake duration was not statistically significant between two groups, as it was comparable in both the groups.

TABLE 3: BASELINE ALCOHOL PROFILE OF STUDY SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
First drink onset (yrs) Mean (S.D)	20.82(5.85)	20.41(5.65)	21.24(6.07)	U=486.50, Z= -.941, p=0.72
Daily drinking onset (yrs) Mean (S.D)	30.52(6.55)	29.97(5.64)	31.09(7.42)	U=526.00, Z= -.442, p=0.66
Duration of alcohol intake (yrs) Mean (S.D)	20.25(9.47)	20.29(9.21)	20.21(9.86)	t=0.35,df=65, p=0.97

ABSTINENT EPISODES PROFILE OF STUDY SAMPLE:

TABLE 4: ABSTINENT EPISODES PROFILE OF STUDY SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Abstinent episodes Mean (S.D)	3.69 (4.41)	2.91 (3.62)	4.48(5.03)	U=404.50, Z= -2.01, p=0.045*
Length of abstinence Mean (S.D)	197.93 (296.63)	189.85 (282.68)	206.24(314.55)	U=482.00, z=-.99, p=0.32

Patients in the TCC group had lesser number of abstinent episodes than TAU group; however there was no statistical difference in the mean length of abstinence. (table.No.4)

HISTORY OF COMPLICATED WITHDRAWAL SYMPTOMS:

TABLE 5:BASELINE HISTORY OF COMPLICATED WITHDRAWAL SYMPTOMS

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Withdrawal seizures n(%)				
Absent	56(83.6)	29(85.3)	27(81.8)	2=0.147, df=1, p=0.70
Present	11(16.4)	5(14.7)	6(18.2)	
Delirium tremens n (%)				
Absent	49(73.1)	22(64.1)	27(81.8)	2=2.50, df=1, p=0.14
Present	18(26.1)	12(35.3)	6(18.2)	
Withdrawal psychotic disorder n(%)				
Absent	63(94)	31(91.2)	32(97)	2=1.001, df=1, p=0.61
Present	4(6)	3(8.8)	1(3)	

History of delirium tremens was present in 26.1 % of patients and 16.4% had history of withdrawal seizures. There was no statistical significance between two groups with respect to alcohol withdrawal profile.

BASELINE ALCOHOL SEVERITY PROFILE OF SAMPLE:

SCID SCORE:

Structured Clinical Interview for DSM IV (SCID) dependence module has 7 criteria and our patients fulfilled at least 6 out of the 7 criteria. Average SCID criteria fulfilled was 6.07 and Mann-Whitney U test didn't detect any statistical difference between TCC and TAU groups (Table 6)

SADQ SCORE:

Mean SADQ score of total sample was 29.82, indicating alcohol dependence of moderate severity. Both TCC and TAU groups had similar mean SADQ profile (Table.6)

SADQ GRADE:

Patients recruited belong to mostly moderate and severe grade of alcohol dependence (46.3 % were of moderate dependence and 44% were of severe dependence).

Hence the severity of alcohol dependence in the TCC and TAU groups was similar.

TABLE 6 :BASELINE ALCOHOL SEVERITY PROFILE OF SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
SCID (No. of criteria fulfilled) Mean(S.D)	6.07(0.96)	6.03(0.93)	6.12(0.93)	U=528.50, Z= -.432, p=0.66
SADQ Score Mean(S.D)	29.82(11.03)	30.32(10.27)	29.30(11.90)	t=0.376, df=65, p=0.70
SADQ Grade n(%)				
Mild	6(9)	2(5.9)	4(12.1)	2=0.82,
Moderate	31(46.3)	16(47.1)	15(45.5)	df=2,
Severe	30(44.8)	16(47.1)	14(42.4)	p=0.66

BASELINE MOTIVATION PROFILE OF STUDY SAMPLE:

Motivation level at baseline was assessed by URICA-University of Rhode Island Change Assessment scale.

URICA SCORE and URICA GRADE:

Mean URICA score of total subjects was 11.74 and 58.2 % of total patients recruited had higher level of motivation i.e. action phase. Both the groups had almost similar proportion of patients in each level of motivation as shown in above Table.7

TABLE 7:BASELINE MOTIVATION PROFILE OF STUDY SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
URICA Score Mean(S.D)	11.74(2.58)	11.65(2.81)	11.83(2.36)	U=558.00, Z= -.038, p=0.97
URICA Grade n(%)				
Precontemplation	7(10.4)	4(11.8)	3(9.1)	2=0.20,
Contemplation	21(31.3)	11(32.4)	10(30.3)	df=2,
Action	39(58.2)	19(55.9)	20(60.66)	p=0.90

DEADDICTION TREATMENT:

Patients admitted in de-addiction ward underwent initial detoxification and then full de-addiction treatment which comprises of motivational interviews, cue analysis and cue management, covert sensitisation, aversion therapy, group therapy and family therapy.

Although there were differences in the components of de-addiction treatment received by patients, there were no statistical difference between TCC group and TAU group.

TABLE 8: DEADDICTION TREATMENT PROFILE OF STUDY SAMPLE:

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
DETOXIFICATION				
Absent	11(16.4)	6(17.6)	8(24.2)	2=0.08, df=1, p=0.78
Present	56(83.6)	28(82.4)	25(75.8)	
MOTIVATIONAL INTERVIEWS				
Absent	2(3)	2(5.9)	-	2=2.001, df=1, p=0.49
Present	65(97)	32(94.1)	33(100)	
CUE ANALYSIS				
Absent	41(61.2)	22(64.7)	19(7.6)	2=0.35, df=1, p=0.55
Present	26(38.8)	12(35.3)	14(42.4)	
AVERSION THERAPY				
Absent	35(52.2)	18(52.9)	17(51.5)	2=0.014, df=1, p=0.90
Present	32(47.8)	16(47.1)	16(48.5)	
COVERT SENTISATION				
Absent	60(89.6)	31(91.2)	29(87.9)	2=0.19, df=1, p=0.70
Present	7(10.4)	3(8.8)	4(12.1)	
FAMILY &GROUP THERAPY				
Absent	4(6)	2(5.9)	2(6.1)	2=0.01, df=1, p=1.00
Present	63(94)	32(94.1)	31(93.9)	

DURATION OF HOSPITAL STAY:

TABLE 9: HOSPITAL STAY DURATION

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Hospital stay duration Mean (S.D)	14.34(4.65)	13.50(6.53)	15.21(6.76)	U=462.00, Z= -1.245, p=0.21

Mean length of hospital for total subjects was 14.34 days. Treatment-as-usual group had slightly longer mean hospital stay of 15.21 days in contrast to 14.34 days of telephone continuing care, but it was not statistically significant.

BENZODIAZEPINE USAGE OF STUDY SAMPLE:

Only 76.1% of patients admitted received benzodiazepine. Others did not required benzodiazepine for detoxification or prescribed some other drugs during treatment. Benzodiazepine usage was comparable in both the groups.

TABLE 9: BENZODIAZEPINE USAGE DETAILS OF STUDY SAMPLE

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
<u>BZD USAGE</u>				
<u>N (%)</u>				
Absent	16(23.9)	8(23.5)	8(24.2)	2=0.05, df=1, p=0.95
Present	51(76.1)	26(76.5)	25(75.8)	

ABSTINENCE MAINTAINING MEDICATIONS:

TABLE 11:ABSTINENT MAINTAINING MEDICATIONS

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Abstinence maintaining medications n(%)				
Present	38(56.7)	18(52.9)	20(60.6)	2=0.40, df=1, p=0.52
Absent	29(43.3)	16(47.1)	13(39.4)	

At the time of discharge, 56.7% of study subjects were prescribed abstinent medications. Of these, 37.3 % of them were prescribed disulfiram and the remaining were prescribed naltrexone, baclofen and acamprosate. But there

was no statistical difference between choices of abstinent medications between two groups.

Thus, there were no significant differences in the intensity and components of in-patient de-addiction received by patients belonging to TCC group and TAU group. At the time of discharge also they received similar abstinent maintaining medications.

2.PRIMARY OUTCOME MEASURES

Primary outcome measures were

- 1) Abstinence
- 2) Occasional drinking
- 3) Daily drinking
- 4) Daytime drinking

At the end of first month 20.9% of patients had relapsed and 79.1% remained abstinent. On subsequent months, abstinence rate gradually declined and at the end of 6 months it was 61.7%. At the end of 6 months, Telephone Continuing Care group having slightly higher abstinent rate of 66.7% compared to 55.6% of Treatment-As-usual group; however this didn't reach statistically significance ($p=0.35$).

TABLE 12: ABSTINECE AND RELAPSE OUTCOME IN TCC AND TAU GROUPS:

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
<u>FIRST MONTH</u>				
Abstinent	53(79.1)	27(79.4)	26(78.8)	2=3.82,
Occasional drinking	3(4.5)	-	3(9.1)	df=2,
Daytime drinking	11(16.4)	7(20.6)	4(12.1)	p=0.15
<u>SECOND MONTH</u>				
Abstinent	50(74.6)	26(76.5)	24(72.7)	2=2.26,
Occasional drinking	5(7.5)	1(2.9)	4(12.1)	df=3,
Daily drinking	2(3)	1(2.9)	1(3)	p=0.52
Daytime drinking	10(14.9)	6(17.6)	4(12.1)	
<u>THIRD MONTH</u>				
Abstinent	44(65.7)	23(67.6)	21(63.6)	2=1.27,
Occasional drinking	6(9.0)	4(11.8)	2(6.1)	df=2,
Daytime drinking	17(25.4)	7(20.6)	10(30.3)	p=0.53

TABLE 13: ABSTINECE AND RELAPSE OUTCOME IN TCC AND TAU GROUPS:

Outcome variables	Total Subjects N=67	Telephone continuing Care N =34(%)	Treatment as usual N =33(%)	Statistics
<u>FOURTH MONTH</u>				
Abstinent	41(65.1)	22(66.7)	19(63.3)	2=2.48, df=3, p=0.48
Occasional drinking	5(7.9)	4(12.1)	1(3.3)	
Daily drinking	2(3.2)	1(3)	1(3.3)	
Daytime drinking	11(23.8)	6(18.2)	9(30)	
<u>FIFTH MONTH</u>				
Abstinent	37(60.7)	20(60.6)	17(60.7)	2=0.50, df=3, p=0.92
Occasional drinking	6(9.8)	4(12.1)	2(7.1)	
Daily drinking	2(3.3)	1(3)	1(3.6)	
Daytime drinking	16(26.2)	8(24.2)	8(28.6)	
<u>SIXTH MONTH</u>				
Abstinent	37(61.7)	22(66.7)	15(55.6)	2=3.29, df=3, p=0.35
Occasional drinking	4(6.7)	2(6.1)	2(7.4)	
Daily drinking	2(3.3)	2(6.1)	-	
Daytime drinking	17(28.3)	7(21.2)	10(37)	

ABSTINENCE RATE BETWEEN TWO GROUPS :

FIG 2 :COMPARISON OF ABSTINENCE BETWEEN TWO GROUPS

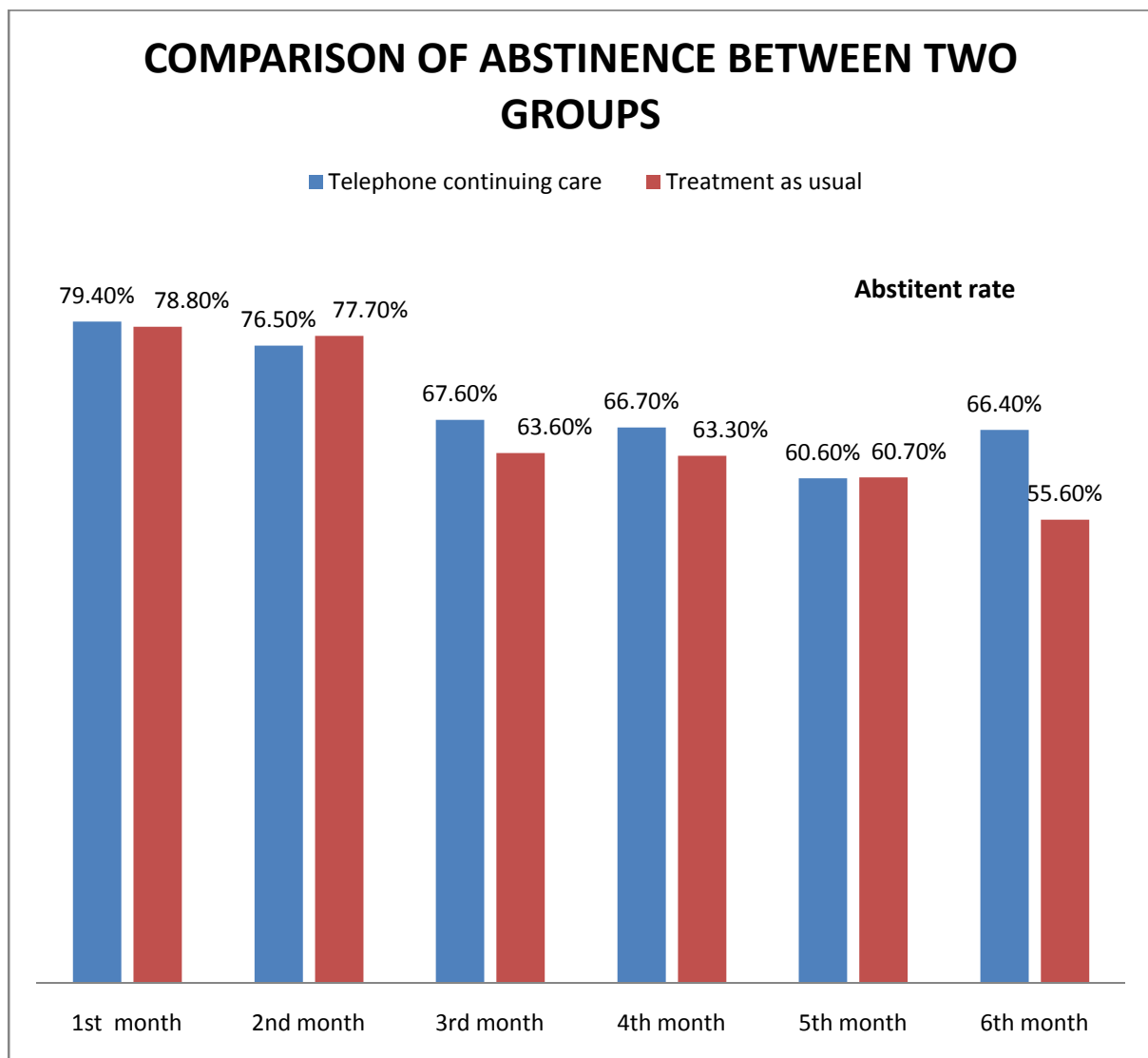


Fig 2 above shows the comparison of abstinence rate between two groups at the end of each month but there was no statistical significant difference between two groups across each month.

3.SECONDARY OUTCOME MEASURES

3.1.ONSET OF FIRST DRINK AFTER DISCHARGE:

Mean onset of first drink of patients who underwent de-addiction treatment was 64.22 days after discharge. There was difference of 7.32 days between two groups but it was not statistically significant ($p=0.11$) as shown below in the table 13.

**TABLE 14: COMPARISON OF ONSET OF FIRST DRINK AFTER DISCHARGE
BETWEEN TWO GROUPS:**

VARIABLES	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Onset of first drink(in days) Mean(S.D)	64.22(53.9)	60.06(56.82)	67.38(52.76)	U=424.00, z=-1.61, p=0.11

TABLE 15: DRINKING PERCENTAGE DAYS IN TWO GROUPS:

Months	Total Drinking percentage days Mean % (S.D)	TCC Drinking percentage days Mean % (S.D)	TAU Drinking percentage days Mean % (S.D)	Statistics
FIRST MONTH Total relapsed pts -14	43.08(25.56)	40.45(22.14)	45.70(30.15)	U=555.50, z=-0.097, p=0.92
SECOND MONTH Total relapsed pts -19	42.63(30.47)	47.60(28.15)	38.17(33.25)	U=545.00, z=-0.252, p=0.80
THIRD MONTH Total relapsed pts -27	36.24(30.88)	36.40(29.04)	36.09(33.59)	U=542.00, z=-0.269, p=0.78
FOURTH MONTH Total relapsed pts -27	37.52(27.43)	44.79(26.07)	31.70(27.96)	U=456.00, z=-0.595, p=0.55
FIFTH MONTH Total relapsed pts -30	37.76(27.33)	43.76(26.25)	32.51(28.00)	U=431.00, z=-0.481, p=0.63
SIXTH MONTH Total relapsed pts -32	38.78(27.30)	47.06(24.28)	32.34(28.42)	U=385.00, z=-0.948,p=0.34

There was cumulative increase in the relapse rates during successive months of follow-up and at the end of 6 months there were 32 patients who had relapsed into drinking. Among these patients, we calculated drinking percentage days as: Number of drinking days/Total days. As shown above in the Table. No. 15, there was no significant difference between two groups with respect to mean drinking percentage days at each month.

3.3. DRUG COMPLIANCE:

Telephone continuing care group had **higher drug compliance** compared to treatment-as-usual group. Mean drug compliance in telephone group was **91.44 days** compared to **63.18 days**, which was statistically significant with p value of 0.03

TABLE 16: COMPARISON OF DRUG COMPLIANCE BETWEEN TWO GROUPS

OUTCOME VARIABLE	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Drug compliance(in days) Mean (S.D)	77.52 (65.52)	91.44 (63.76)	63.18 (65.15)	U=393.50, z=-2.11, p=0.03*

3.4.LENGTH OF FOLLOW UP:

Mean length of follow up of total subjects was 80.40 days. **‘Telephone continuing care’** had **longer follow-up of 99.65 days** compared to **60.58 days** in ‘treatment-as-usual’ group and this showed a trend toward significance.

TABLE 17: COMPARISON OF LENGTH OF FOLLOW- UP BETWEEN TWO GROUPS

OUTCOME VARIABLE	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Length of follow up (days) Mean (S.D)	80.40 (70.53)	99.65 (67.55)	60.58 (68.97)	U=347.00, z=-2.73, p=0.06

3.5.GROUP VISITS ATTENDANCE:

In comparing attendance for group visits between two groups, there was statistical significance with p value of 0.05. Telephone continuing care group had higher number of mean group visits (1.29) compared to mean of 0.58 visits in treatment-as-usual group

TABLE 18: COMPARISON OF GROUP VISITS ATTENDANCE BETWEEN TWO

GROUPS:

OUTCOME VARIABLE	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Group visits N (%)	0.94 (1.19)	1.29 (1.29)	0.58 (0.96)	U=354.50, z=-2.78, p=0.05*

3.6. READMISSIONS AFTER DISCHARGE:

19.4 % of total subjects had readmissions after discharge for lapse of drinking during study period. Of those, there were 6 patients belonging to telephone continuing care group and 7 patients belonging to treatment-as-usual group, which was not statistically significant ($p=0.58$).

TABLE 19: COMPARISON OF RE-ADMISSIONS BETWEEN TWO GROUPS:

OUTCOME VARIABLE	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
No of re-admissions (no of patients)(%)				
Nil	54(80.6)	28(82.4)	26(78.8)	2=1.05, df=2, p=0.58
Single	12(17.9)	6(17.6)	6(18.2)	
>1	1(1.5)	-	1(3)	

DROP-OUTS BETWEEN TWO GROUPS:

TABLE 20: COMPARISON OF DROP-OUTS BETWEEN TWO GROUPS

OUTCOME VARIABLE	TOTAL SUBJECTS N=67	TELEPHONE CONTINUING CARE(TCC) N=34(%)	TREATMENT AS USUAL(TAU) N=33(%)	Statistics
Drop –outs	7(10.6)	1(2.9)	6(18.8)	2=4.34,df=1, p=0.05*
Completers	60 (89.6)	33(97.1)	26(81.3)	

There was higher drop-out rate of 18.8% in treatment-as-usual group compared to 2.9% in telephone continuing care, which was statistically significant with p value of 0.05.

COMPLETERS

Among 67 total subjects, we were able to follow-up and obtain complete information for 60 patients and we call them as “**Completers**”. At the end of 6 months, among the completers, 28 patients (46.7%) remained as completely abstinent and 32 patients (53.3%) relapsed into drinking. We call the former as ‘**Abstinence group**’ and latter as ‘**Relapse group**’.

We assessed the drinking percentage days in the **Relapse group** and compared them with their baseline drinking percentage days.

3.2. DRINKING FREQUENCY OF RELAPSED PATIENTS

At the end of each month, there was significant reduction in drinking percentage percentages of patients who had relapsed after discharge from hospital, which was also statistically significant with p value of 0.0001 at each month.

**TABLE 21 : COMPARISON OF DRINKING FREQUENCY WITH THEIR
BASELINE**

MONTHS	TOTAL RELAPSED PATIENTS	DRINKING DAYS MEAN (%)	MEAN REDUCTION FROM BASELINE	95 % C.I	STATISTICS
FIRST	14	43.08(25.56)	-56.92	-71.68 to -42.16	t=-8.832,df=13, p=0.0001
SECOND	19	42.63(30.47)	-57.36	-72.05 to -42.67	t=-8.204,df=18, p=0.0001
THIRD	27	36.24(30.88)	-63.73	-75.97 to -51.54	t=-10.728,df=26, p=0.0001
FOURTH	27	37.52(27.43)	-62.47	-73.33 to -51.62	t=-11.83,df=26, p=0.0001
FIFTH	30	37.76(27.33)	-62.23	-72.44 to -52.02	t=-12.47,df=29, p=0.0001
SIXTH	32	38.78(27.30)	-61.21	-71.05 to -51.36	t=-12.68,df=31, p=0.0001

At the end of first month after discharge, there was almost 56.92% reduction in drinking days compared to baseline 100 % drinking days. Reduction in drinking days percentages gradually climbs as months progress with statistical significance of $p=0.0001$ at each month.

At the end of sixth month, there was almost 61.21% reduction in drinking days compared to baseline 100 % drinking days, which was also statistically significant. ($p=0.0001$)

PREDICTORS OF RELAPSE IN COMPLETERS

BIVARIATE ANALYSIS:

Possible factors that would predict risk of relapse were analysed using bivariate analysis and multiple logistic regression .

Factors such as study arm, caregiver telephone status, basic socio-demographic details, family history of alcoholism, baseline alcohol profile, alcohol severity, motivation level, treatment details, abstinent medications, hospital stay duration, drug compliance, group visit attendance and length of follow-up were analysed for possible association with abstinence and relapse.

4.1. STUDY GROUP AND RELAPSE:

There was trend towards significance with p value of 0.06 on analysing the association of interventional group with relapse for those who completed the study. Telephone continuing care group had lesser proportion of patients relapsing into drinking in the 6 months follow-up.

TABLE 22: ASSOCIATION OF STUDY GROUP AND RELAPSE RISK

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N =32 (%)	STATISTICS
<u>GROUP</u>			
Telephone continuing care	19(67.9)	14(43.8)	2=3.50, df=1, p=0.06
Treatment as usual	9(32.1)	18(56.3)	

4.2. SOCIODEMOGRAPHIC PROFILE AND RELAPSE RISK:

TABLE 23: ASSOCIATION OF SOCIODEMOGRAPHIC FACTORS AND RELAPSE:

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N=32 (%)	STATISTICS
AGE Mean(S.D)	40 .00(7.67)	41.28(8.73)	t=-.603, df=58, p=0.54
MARITAL STATUS Married Unmarried Separated	26(92.9) 1(3.6) 1(3.6)	29(90.6) 3(9.4) -	2=1.92, df=2, p=0.38
EDUCATION Graduate High school & diploma Intermediate school Illiterate	1(3.2) 16(51.6) 13(41.9) 1(3.2)	7(19.4) 12(33) 16(44.4) 1(2.8)	2=5.03, df=3, p=0.16
OCCUPATION Profession Self employed Skilled Unskilled	5(7.8) 28(41.8) 31(46.3) 3(4.5)	4(11.1) 16(44.) 15(41.7) 1(2.8)	2=2.37, df=3, p=0.49

As shown in the above Table.No.22, there was no statistical significant association between age, age, marital status, socio-economic status and **Relapse.**

4.3. OTHER SUBSTANCE USE AND RELAPSE RISK

On analysing the association of smoking status, number of cigarettes and other comorbid substance usage with relapse risk in patients who completed the study, there was no statistical significance of association seen with either of these factors as shown in the below Table No. Similarly, comorbid physical illness did not found to have significant association regarding relapse risk.

FAMILY HISTORY AND RELAPSE RISK:

But positive family history of alcoholism had trend towards significant association with predicting higher chances of relapse. Patients having positive family history in more than one member had higher chance of relapse (40.6 %) compared to being abstinent (14.3) with p value of 0.07.

TABLE 24: ASSOCIATION OF OTHER BASELINE DETAILS AND RELAPSE

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N =32 (%)	STATISTICS
SMOKING STATUS			2=.15,
Present	18(64.3)	19(59.4)	df=1,
Absent	10(35.7)	13(40.6)	p=0.69
OTHER SUBSTANCE USE			2=2.03,
Present	25(89.3)	24(75)	df=1,
Absent	3(10.7)	8(25)	p=0.15
<u>COMORBID PHYSICAL ILLNESS</u>			2=0.021,
Present	18(64.3)	20(62.5)	df=1,
Absent	10(35.7)	12(37.5)	p=0.88
<u>FAMILY HISTORY OF ALCOHOLISM</u>			2=5.14,
Nil	7(25.0)	5(15.6)	df=2,
Single member	17(60.7)	14(43.8)	p=0.07
>1 member	4(14.3)	13(40.6)	

4.5.ASSOCIATION OF CLINICAL FEATURES OF ALCOHOL AND RELAPSE:

TABLE 25: ASSOCIATION OF ALCOHOL PROFILE AND RELAPSE:

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N =32 (%)	STATISTICS
ONSET OF FIRST DRINK	21.21(6.49)	20.50(5.71)	U=426.00,z=-.33,p=0.74
DAILY DRINKING ONSET	30.46(5.77)	30.59(7.44)	t=-.07,df=58,p=0.94
DURATION OF ALCOHOL INTAKE	18.79(8.41)	20.81(9.75)	t=-.85,df=58,p=0.39
PAST HISTORY OF LENGTH OF ABSTINENCE	160.75(224.07)	208.19(296.64)	U=393.00,z=-.81,p=0.41
WITHDRAWAL SEIZURES			2=.05,
Absent	23(82.1)	27(84.4)	df=1,
Present	5(17.9)	5(15.6)	p=1.00
DELIRIUM TREMENS			2=.37,
Absent	19(67.9)	24(75)	df=1,
Present	9(32.1)	8(25)	p=0.54
WITHDRAWAL PSYCHOTIC DISORDER			2=1.38,
Absent	25(89.3)	31(96.9)	df=1,
Present	3(10.7)	1(3.1)	p=0.24
SADQ SCORE	28.50(10.85)	30.31(10.74)	t=-.64,
Mean (S.D)			df=58, p=0.52

Among **Completers**, none of the alcohol profile factors, such as onset of first drink, onset of daily drinking , duration of alcohol intake and abstinent episodes were found to statistically significant in influencing the relapse (shown above in Table.)

Similarly, history of withdrawal seizures ,delirium tremens and withdrawal related psychotic disorder were not found to be having any significant association with abstinence and relapse.

On analysing the association of baseline alcohol severity profile factors such as SCID score, SADQ score and SADQ grade with abstinence, there was no statistical significant association with baseline alcohol profile and abstinence as shown above in the Table No.

4.9. ASSOCIATION OF TREATMENT VARIABLES AND RELAPSE:

TABLE 26: ASSOCIATION OF TREATMENT VARIABLES AND RELAPSE

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N =32 (%)	STATISTICS
URICA GRADE			
Precontemplation	4(14.3)	3(9.4)	2=1.50, df=2, p=.45
Contemplation	10(35.7)	8(25)	
Action	14(50)	21(65.6)	
HOSPITAL STAY DURATION			
Mean (S.D)	15.68(6.95)	13.25(6.25)	U=353.00, z=-1.41, p=.15
ABSTINENCE MAINTAINING MEDICATIONS			
N(%)			2=1.24, df=1, p=0.26
Absent	10(35.7)	16(51.6)	
Present	18(64.3)	16(50)	
Length of hospital admission			
>3 weeks	12(42.9)	6(18.8)	2=4.13, df=1, p=0.042*
< 3 weeks	16(57.1)	26(81.3)	

Motivational level assessed by URICA was also analysed for possible association with abstinence model, but neither URICA score nor URICA grade was found to be statistically significant in predicting abstinence.

Treatment profile factors such as benzodiazepine use, mean duration of hospital stay and abstinent medications were analysed for possible influence on outcome. But neither of the factors was found to be having any predicting influence on abstinence.

81.3 % of patients who had relapsed had hospital admission less than 3 weeks whereas 66.67 % of patients admitted atleast three weeks were found to be remaining abstinent. Length of hospital admission more than or equal to three weeks was found to be having positive predicting influence on outcome.

While hospital admission less than 3 weeks was found to be having three times higher chance of relapse (Odds Ratio of 3.25 and 95% C.I of 1.018 TO 10.379).

4.12. ASSOCIATION OF FOLLOW UP TREATMENTS AND RELAPSE:

TABLE 27: ASSOCIATION OF FOLLOW UP TREATMENTS AND RELAPSE:

VARIABLES	ABSTINENCE GROUP N=28 (%)	RELAPSE GROUP N =32 (%)	STATISTICS
DRUG COMPLIANCE	123.21(59.07)	42.09(45.46)	U=129.50, z=-4.76, p=0.0001*
GROUP VISITS	1.39(1.44)	0.59(0.79)	U=306.50, z=-2.25, p=0.024*
LENGTH OF FOLLOW UP	107.14(68.5)	62.19(69.33)	U=271.50, z=-2.68, p=0.008*

Patients having higher drug compliance, higher attendance for group visits and longer follow-up were found to be statistically significant in predicting the abstinence with p values of 0.0001, 0.024 and 0.008 respectively.

MULTIPLE LOGISTIC REGRESSION:

4.13.RESULTS OF MULTIPLE LOGISTIC REGRESSION:

TABLE 28: MULTIPLE LOGISTIC MODEL OF RELAPSE RISK

VARIABLES	B	S.E	SIGNIFICANCE	EXP(B)
Demographic details				
Age	0.055	0.076	0.468	
Marital status (single/separated)	3.243	2.763	0.240	25.605
Socioeconomic status	0.000	0.000	0.463	
Smoking status	-1.321	0.997	0.852	
Family history of alcoholism				
>1 member	3.170	1.279	0.013*	23.813
=1 member	1.824	1.026	0.075	6.199
Alcohol profile				
SADQ score	0.046	0.042	0.273	
Duration of alcohol intake	-0.056	0.075	0.458	
Motivation profile				
URICA score	0.255	0.203	0.209	
Treatment profile				
Study group	0.493	0.908	0.587	1.637
Duration of hospital stay	0.031	0.076	0.681	
Poor drug compliance	-0.039	0.011	0.0001	

For our logistic model, on applying Hosmer and Lemeshow test, p value came as 0.263 and hence logistic regression analysis is possible. Omnibus tests of model coefficients, p value is <0.0001 ; hence our logistic model is a significant model to predict relapse.

Possible confounding variables such as age, marital status, socio-economic status, smoking status, family history of alcoholism, baseline alcohol profile, baseline motivational level, study group, duration of hospital stay and drug compliance were entered as co-variates keeping **Relapse** as dependent variable in the multiple logistic regression analysis.

Family history of alcoholism and drug compliance was found to be statistically significant in predicting the relapse risk. Positive family history of alcoholism in one member was found to be having trend towards significance in predicting relapse whereas **positive family history in more than one family** members was found to be having higher risk of relapse with statistical significance of **p value =0.013** and odds ratio of 23.813.

Poor drug compliance was another factor significantly predicting relapse with **p value of 0.0001**.

DISCUSSION

Our randomized controlled study was designed to evaluate the effectiveness of telephone continuing care in managing alcohol dependence syndrome. Also, the 6 month data obtained for the whole group was used to build a model that would predict relapse.

To start with, we had recruited a homogenous patient population who fulfilled the DSM IV TR criteria for alcohol dependence and admitted for de-addiction treatment. Their baseline socio-demographic details, clinical profile and baseline features of alcohol appear to be generalizable as they were similar to other published Indian studies [17, 37, 38].

The mean age of our patient group was 41.10 years and they had been drinking alcohol since the age of 20 and for at least for the last 10 years they had been drinking daily. As rated by SADQ, most of them (91%) had moderate to severe dependence. Most of them (58.2 %) had action level of motivation, as assessed by URICA.

Table 29: Comparison of demographic and baseline alcohol profile of our study sample with other Indian outcome studies

Variable	Our Study Results	Kar et al,2003	Chandrasekaran et al,2001	Abraham et al,1997
Mean age (S.D)	41.09 yrs(8.63)	30.8 yrs(8.5)	39.7 yrs(8.66)	39.6 yrs(8.5)
Age of onset of first drink (S.D)	20.82 yrs (5.85)	NA	23.18 yrs (6.92)	23.15(7.2)
Age of onset of daily drinking (S.D)	30.52 yrs (6.55)	29.35 yrs (8.1)	30.07 yrs (8.71)	NA
Duration of alcohol intake (S.D)	20.25 yrs (9.46)	NA	9.71 yrs (7.96)	16.5(6.75)

NA: Not available

Table 30 : Comparison of Positive family history of alcoholism with outcome studies

Variable	Our Study Results	Kar et al,2003	Chandrasekaran et al,2001	Abraham et al,1997
Positive family history of alcoholism	77.6%	66.2 %	67.1%	54.25%

Another interesting finding was 77.6% of recruited patients had positive family history of alcoholism, which was similar to previous Indian outcome studies. [17, 37, 38]

Primary outcome measures:

On analysing the primary outcome measures between the two groups, at the end of 6 months, **complete abstinence rate was 66.4% in Telephone continuing care (TCC) group and 55.6% in Treatment-as-usual group (TAU).** Though numerically TCC group appears better than TAU group, this difference didn't stand up to statistical significance. The same scenario was seen at each month of assessment as shown in the table 37.

Table 31 : Comparison of abstinence rate between two groups at each month

	Telephone continuing care	Treatment as usual	P value
1 st month	79.4%	78.8%	0.15
2 nd month	76.5%	77.7%	0.52
3 rd month	67.6%	63.6%	0.52
4 th month	66.7%	63.6%	0.48
5 th month	60.6%	60.7%	0.92
6 th month	66.4%	55.6%	0.35

However, in the **Completers** group (6 month complete data obtained) the difference in the abstinence rate is even larger. In completers, the abstinence rate in TCC group was 67.9%, whereas in TAU group it was 32.1% and this difference showed trend towards significance ($p=0.06$)

This is in contrast to earlier studies done in the west, which showed a better outcome in telephone continuing care [3, 6, 18, 41]. Mckeller et al [41] studied 667 patients and found that in telephone based continuing care there was a

significant reduction in drinking percentage days. Our study couldn't replicate such significance because of small sample size. Another reason could be that our study duration was short. McKay et al showed significant better results only in 24 months longer outcome studies [3]. Hence we speculate that a large sample size with longer duration of study the advantage of Telephone continuing care could become significant.

Also in addition, still adequate face to face interviews might be needed to hold on the benefits of telephone continuing care.

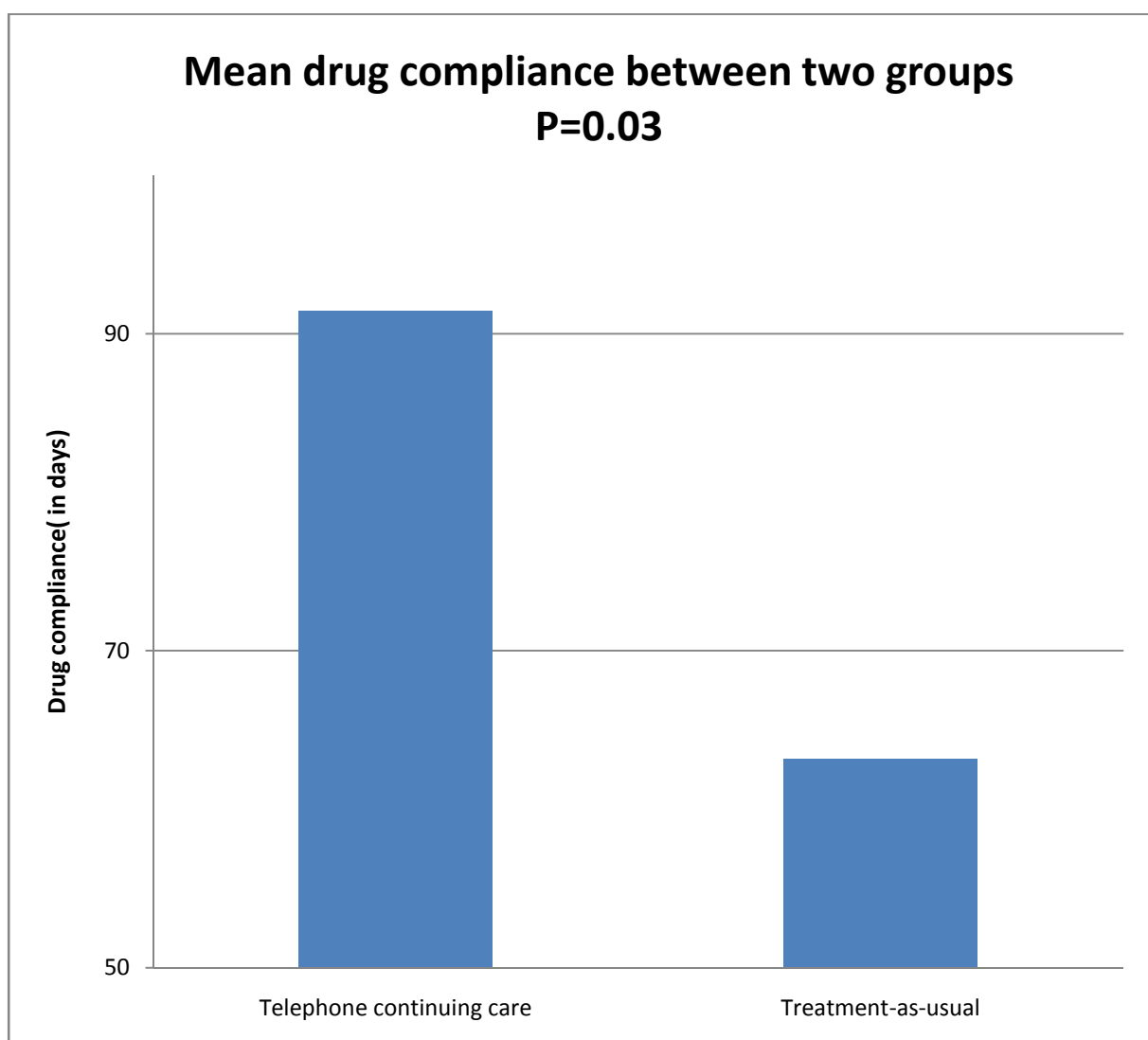
Secondary outcome measure:

Telephone continuing care group performed better than treatment as usual group in terms of **good drug compliance, longer length of follow-ups in clinic and better attendance for group therapy**. There was significant statistical difference between two groups in the above parameters.

Many studies also demonstrated similar results [3, 6]. Godley et al [6] demonstrated better attendance for group visits and follow-up in clinic. Similarly, Mc Keller et al [41] showed better results in telephone group in terms

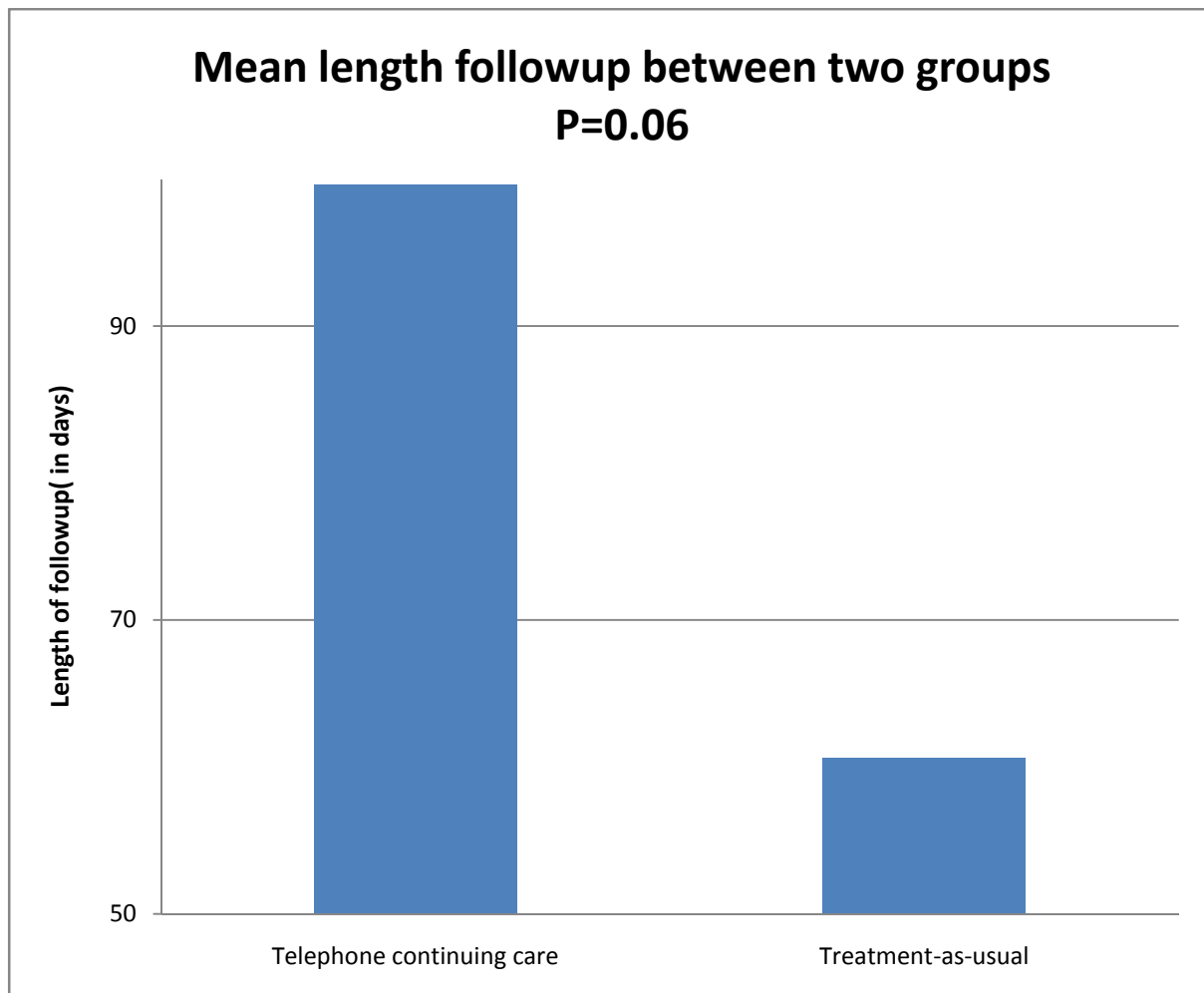
of treatment adherence and follow-up at the end of 3 months. But these results were not replicated at the end of 12 months.

Figure 3: Comparison of drug compliance between two groups



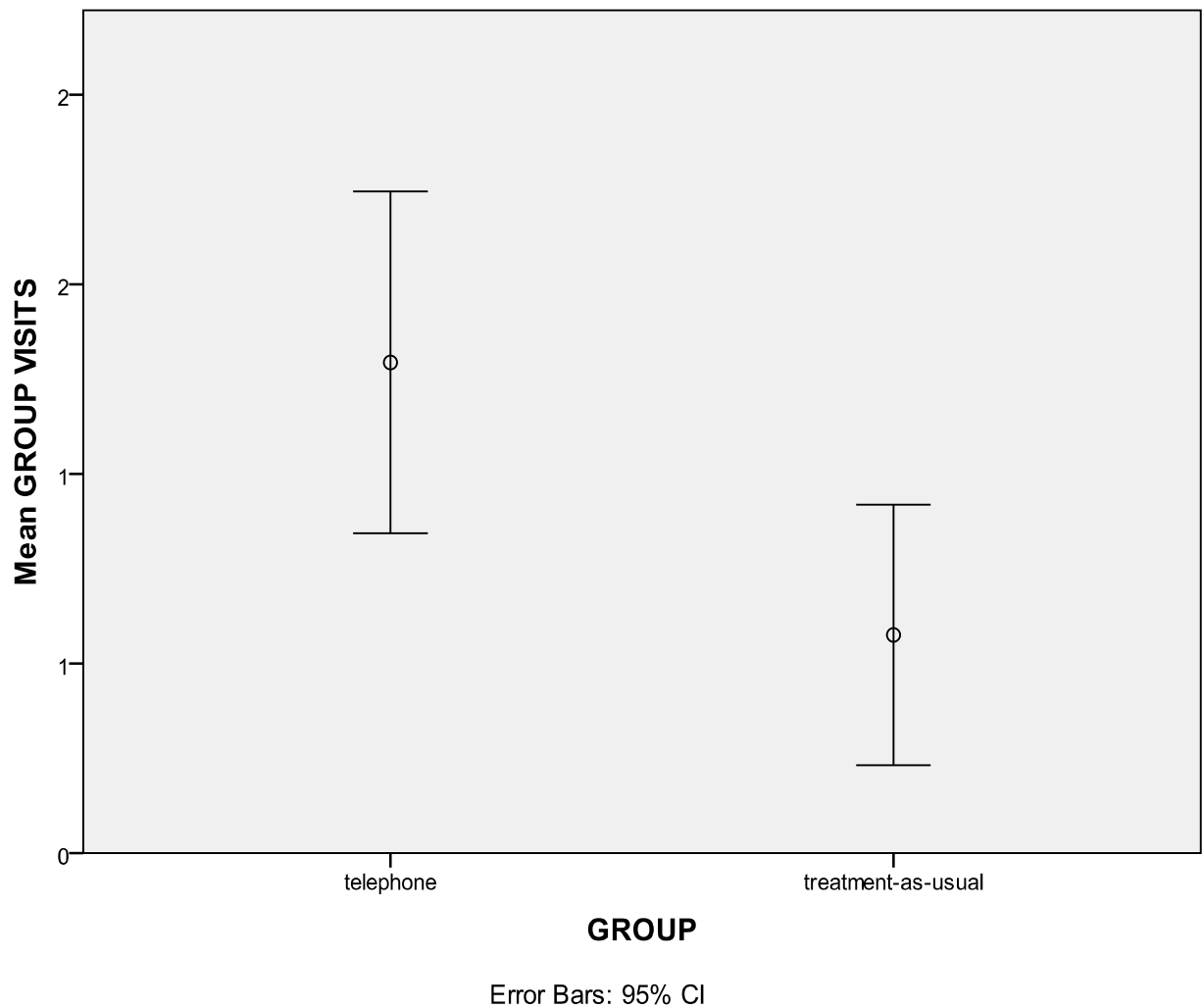
With respect to compliance to drug regimen, telephone continuing care had mean drug compliance of 91.44 days compared to 63.18 days of treatment as-usual group.($p=0.03$).

Figure 4: Comparison of length of follow up between two groups



Similarly, there was trend towards significance in terms of length of follow up between two groups (99.65 days in telephone continuing care group vs 60.58 in treatment-as-usual, $p=0.06$).

Figure 5: Comparison of group visits attendance between two groups



Also, attendance of group visits was higher in telephone continuing care group and there was statistical significance when compared to treatment-as-usual group. (1.29 visits versus 0.58 visits, $p=0.05$)

Regarding other secondary outcome measures such as onset of first drink, drinking days percentages and number of re-admissions, there was no statistical difference between two groups.

EFFECTIVENESS OF DE-ADDICTION TREATMENT:

Our de-addiction treatment regimen includes detoxification, motivational interviews, cue analysis, aversion therapy, covert sensitization, family and group therapy. Finally at the time of discharge, we used to prescribe abstinence medications and advised to come for regular follow-up. Many tertiary centres have de-addiction treatment with the above components [17, 38]

Even though abstinence rate and drinking percentage days among patients who had did not differ statistically between the two groups, the effectiveness of the de-addiction programme for the whole sample was very encouraging. For the whole sample, the complete abstinence rate and drinking percentage days among patients who had relapsed were much better.

COMPLETE ABSTINENCE

Total abstinence rate of the whole group was 61.7%, which was much better than other outcome studies done in India. [17, 38]

Table 32: Comparison of abstinence rate with other outcome studies

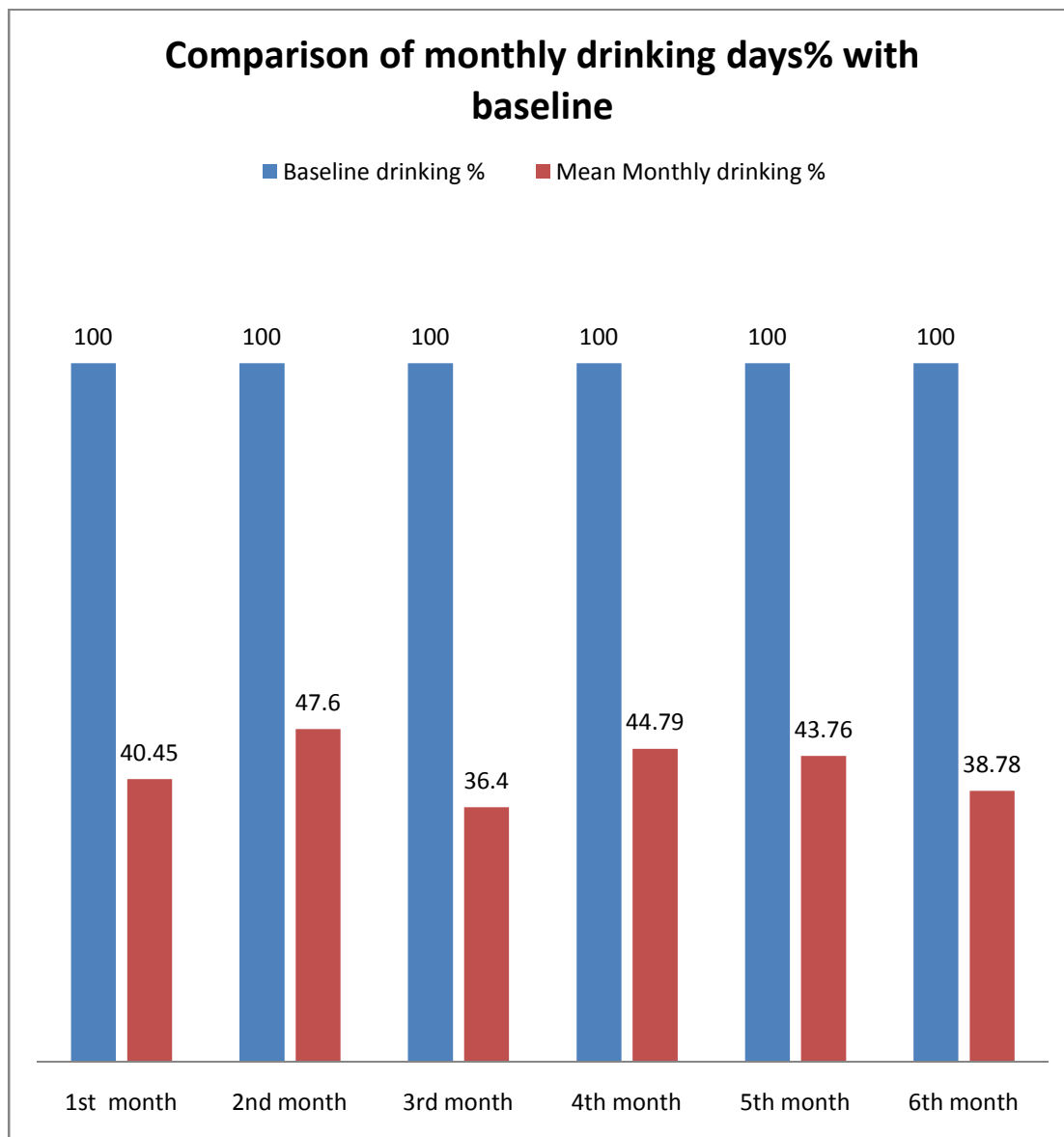
Variable	Our Study Results	Kar et al,2003	Chandrasekaran et al,2001
Abstinent Rate (%)	61.7%	46.7%	32.5%

DRINKING PERCENTAGE DAYS IN RELAPSED PATIENTS:

Drinking percentage days frequency did not show any difference between TCC and TAU groups. Godley et al (6) also published similar outcome; where percentage of days abstinent was similar in telephone intervention group and the control group. However another study demonstrated significant drinking frequency reduction in telephone based group [3].

At baseline, all our patients had moderate to severe dependence and they were drinking everyday; that means their drinking percentage days was 100%. At the end of sixth months, 32 patients had relapsed and even in them there was almost 61.21% reduction in drinking days compared to baseline drinking days, and this was highly statistically significant.($p=0.0001$).

FIGURE 6: COMPARISON OF MONTHLY DRINKING FREQUENCY OF RELAPSED PATIENTS



Three weeks admission:

Duration of hospital stay less than three weeks was found to be associated with higher rate of relapse compared to patients with more than three weeks of hospital stay. Among patients who were hospitalized for more than 3 weeks only 18.8% relapsed whereas among patients who were hospitalized for less than 3 weeks, 81.3 % had relapsed. Length of hospital admission more than or equal to three weeks was found to be having positive predicting influence on outcome. But the same significance was not obtained when analysed using multiple logistic regression.

In contrast to our results, Nesmes et al[42] and Harris et al[44] showed that longer residential treatment did not found to be associated with any positive outcome in alcohol treatment program. Trend et al [43], did a randomized trial, which also showed similar results showing no added benefits over longer stay.

But few naturalistic studies of substance disorders, Bunn et al [45] and Darke et al [46] showed that prolonged hospitalization yields better outcomes such as substance problem usage, readmissions and even premature mortality reduction.[45]

MOTIVATION AND COMPONENTS OF DE-ADDICTION

Motivation level of patients at the time of admission was good and most of them were in action stage. Such a high level of motivation at baseline couldn't differentiate between abstinence and relapse. However Kar et al [38], could show that higher motivation level had positive predictive influence on abstinence.

Though our patients were getting motivational interviews, cue analysis, aversion therapy, covert sensitization, family and group therapy, none of these components could predict abstinence or relapse.

Similarly anti craving drugs or antabuse drugs also couldn't predict abstinence or relapse, which is a very surprising finding. Our patients were getting were disulfiram and anticraving drugs such as baclofen, naltrexone, and acamprosate. These drugs were found to be not having any superior advantage over placebo (Multivitamins).

This is in contrast to Jorgesan et al 2014, [46] who showed better results with Disulfiram in short-term outcome. Likewise, Skinner et al, 2014[47] in his meta-analysis results showed that disulfiram was safe and efficacious compared to other medications in maintaining abstinence. Previous Indian studies [17] also showed favourable outcome in patients on disulfiram. But there were also few recent studies [48] showing no significant role for abstinent medications in treating alcohol dependence.

Tele-counselling:

One of our exclusion criteria was non –availability of telephone connections. It was a pleasant surprise that all the patients whom we screened for this study were having mobile or landline connection. In addition to that, 68.7% of caregivers had additional telephone connection, either mobile or landline.

Both for tele-counselling and assessments we were able to contact them easily. For the entire 6 months, we were able to follow-up 60 out of 67 patients through phone. These indicate the feasibility of out-reach of tele-psychiatry in our country.

DROP-OUTS:

Our study has a very low drop out; only 7 patients (10.4%) dropped out during the 6 month follow-up. One patient (2.9 %) belonged to Telephone continuing care group(TCC) and 6 patients (18.2%) belonged to Treatment –as-usual group(TAU) and this difference was statistically significant at $p=0.05$. This proves that longer contact time through phone could improve treatment adherence.

**FIGURE 7: COMPARISON OF DROP-OUTS BETWEEN TWO GROUPS AT THE
END OF 6 MONTHS**

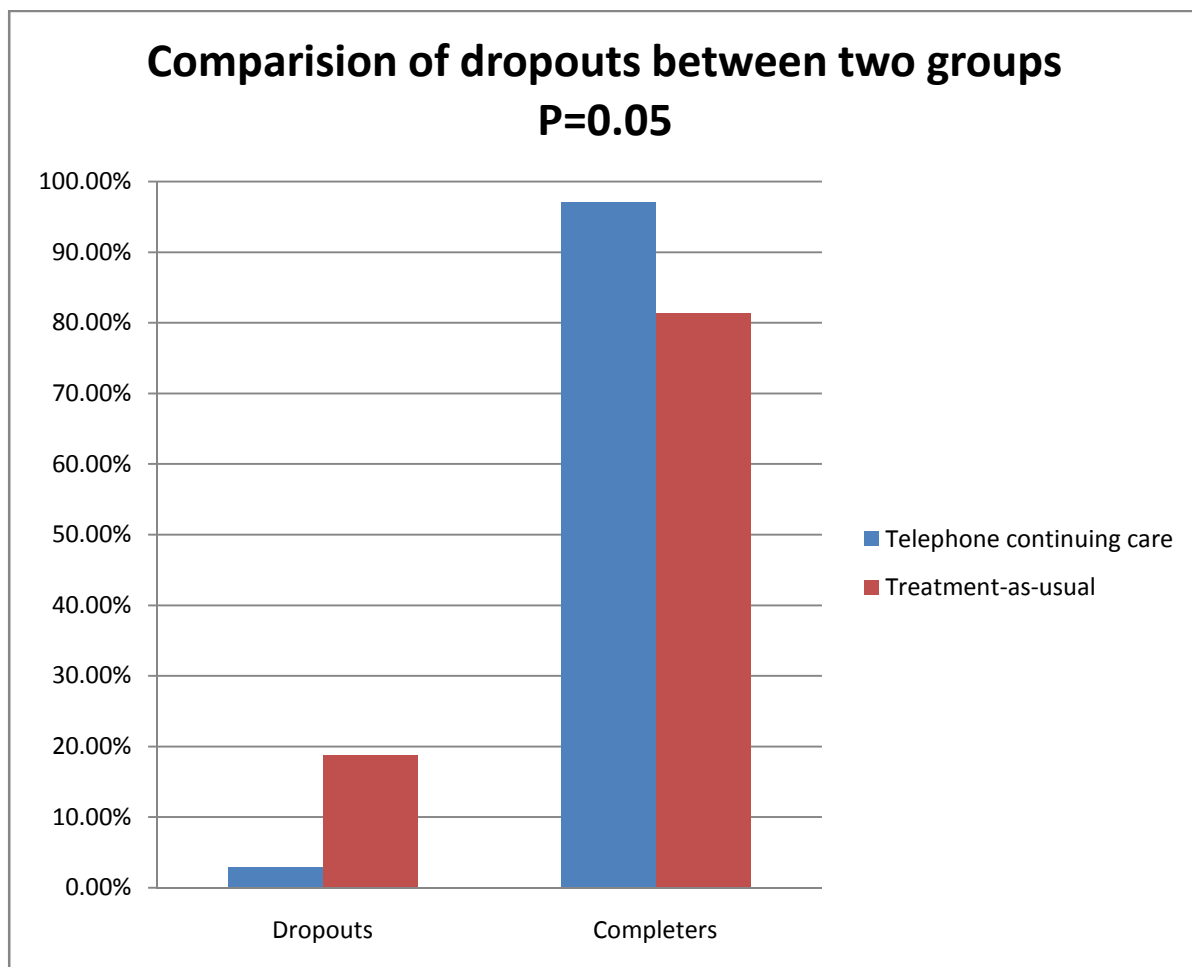


TABLE 33: COMPARISON OF DROPOUTS WITH OTHER OUTCOME STUDIES

Our Study	Chandrasekhar et al,2001	Manipal et al,2003	Abraham et al,1997	Godley et al,2010
10.4% TCC group: 2.9%	87.5%	10%	40%	15%

Compared to other published studies, [6, 7, 37, 38], we had one of the lowest drop-out rates. This could be attributed to the pro-active contact by the researchers to both patients and their care-givers. Longer the pro-active contact time lower the drop-out rates; this is proved by the very low drop-out rate in telephone continuing care group (2.9 %).

MULTIPLE LOGISTIC REGRESSION

Predicting the factors influencing the outcome measures in alcohol de-addiction was always a challenging task considering a high rate of relapse. We considered all the possible compounding factors in our study design that might influence the outcome measures such as abstinence and relapse.

Socio demographic details such as age, marital status, telephone status of caregiver, education, income, occupation did not found to predict relapse. This is in contrast to a previous study, which showed lower socio economic status having a higher risk of relapse [38].

In our patients who had relapsed into alcohol again, 84.4% them a had positive family history of alcoholism. Using multiple logistic regression, family history of alcoholism was found to have a significant predicting influence on relapse. Its predictive value in relapse was found to be even higher when more than one family member had history of alcoholism. (Odds ratio of 23.813,95% C.I 1.94 to 291.90). This association of family history of alcoholism in predicting relapse was also reflected in previous Indian outcome studies [38].

Similarly, drug compliance was found to be predicting maintenance of abstinence. Interesting feature was compliance to even multivitamins was found to be effective in influencing the abstinence. ($p=0.0001$)

No other factors were found to be significant in predicting the outcome measures of alcohol de-addiction strategies

To summarize our results, Telephone continuing care (TCC) showed better results in terms of drug compliance, group visits attendance , length of follow up and marginal benefits in maintaining abstinence. Overall picture showed a significant better outcome with our standard alcohol de-addiction program.

Telephone based continuing care in short run gives promising results, which needed to be evaluated in longer period.

LIMITATIONS:

1. As our study was not a double blind study, there was a possibility of investigator bias.

We tried to minimize the bias by strictly following the study protocol. Our results were more of giving negative outlook to outcome measures in alcohol de-addiction with few significant positive results. Hence, the question of investigator bias in influencing the outcome was minimal but not dismissible.

2. We are not able to reach the target size of 78 patients because of time constraints. But we are able to show significant findings with available sample. But a larger sample might reveal even clearer picture on outcome measures of de-addiction treatment and predictors of abstinence.

3. Attrition rate was 10.6%. We couldn't contact 7 patients and their status of drinking was unknown.
4. The study sample was recruited from psychiatry ward so the results cannot be generalized to the community.
5. Before randomization patients underwent de-addiction treatment, which was provided by different therapists. Even though there was a common alcohol de-addiction treatment model, variation in the clinician approach and treatment could also influence the outcome; this aspect was not studied by us.

CONCLUSION:

Telephone Continuing Care (TCC) improved significantly the duration of follow-up, drug compliance, attendance to group meetings and marginally improved the complete abstinence state.

As drug compliance was one of the good predictors of abstinence, drug compliance being improved by telephone continuing care group is a clinically useful strategy. Another factor which strongly predicted relapse was positive family history of alcoholism.

At the end of 6 months, in the whole sample 61.7% remained completely abstinent and among patients who had relapsed there is a significant reduction in drinking percentage days. This proves the effectiveness of a standard de-addiction programme; however there is still much scope to improve the outcome and more robust telephone continuing care could be a way forward.

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ANNEXURES

APPENDIX 1: SCID QUESTIONNAIRE

SCID-I (for DSM-IV-TR) Alcohol Dependence (JAN 2010) Substance Use Disorders E. 4

ALCOHOL DEPENDENCE		ALCOHOL DEPENDENCE CRITERIA				
<p>► IF DEFINITE PERIOD: Now I'd like to ask you a few more questions about (TIME WHEN DRINKING THE MOST OR HAD PROBLEMS). During that time...</p> <p>► IF NO DEFINITE PERIOD, CHECK FOR LIFETIME USE WITH PHRASES IN ITALICS. Now I'd like to ask you some more questions about your drinking.</p>		<p>A maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same 12-month period:</p> <p>NOTE: CRITERIA FOR ALCOHOL DEPENDENCE ARE NOT IN DSM-IV-TR ORDER</p>				
(Did you often find/Have you often found) that when you started drinking you ended up drinking much more than you were planning to? (Tell me about that.)	(3) alcohol is often taken in larger amounts OR over a longer period than was intended	7	1	2	3	E7
<p>IF NO: What about drinking for a much longer period of time than you were planning to?</p>						
(Did you try/Have you tried) to cut down or stop drinking alcohol?	(4) there is a persistent desire OR unsuccessful efforts to cut down or control alcohol use	7	1	2	3	E8
<p>IF YES: Did you ever actually stop drinking altogether?</p> <p>(How many times did you try to cut down or stop altogether?)</p> <p>IF NO: Did you want to stop or cut down? (Is this something you kept worrying about?)</p>						
(Did you spend/Have you spent) a lot of time drinking, being high, or hung over? (How much time?)	(5) a great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects	7	1	2	3	E9
(Did you have times/Have you had times) when you would drink so often that you started to drink instead of working or spending time at hobbies or with your family or friends, or engaging in other important activities, such as sports, gardening, or playing music?	(6) important social, occupational, or recreational activities given up or reduced because of alcohol use	7	1	2	3	E10

APPENDIX 2: DSM –IV-TR Alcohol dependence criteria-Diagnostic code 303.90

DSM-IV Criteria for Alcohol Dependence:

A maladaptive pattern of alcohol use, leading to clinically significant impairment or distress, as manifested by three or more of the following seven criteria, occurring at any time in the same 12-month period:

1. Tolerance, as defined by either of the following:
 - a) A need for markedly increased amounts of alcohol to achieve intoxication or desired effect.
 - b) Markedly diminished effect with continued use of the same amount of alcohol.
2. Withdrawal, as defined by either of the following:
 - a) The characteristic withdrawal syndrome for alcohol (refer to DSM-IV for further details).
 - b) Alcohol is taken to relieve or avoid withdrawal symptoms.
3. Alcohol is often taken in larger amounts or over a longer period than was intended.
4. There is a persistent desire or there are unsuccessful efforts to cut down or control alcohol use.
5. A great deal of time is spent in activities necessary to obtain alcohol, use alcohol or recover from its effects.
6. Important social, occupational, or recreational activities are given up or reduced because of alcohol use.
7. Alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the alcohol (e.g., continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

Appendix 3: SADQ –C SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE

SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE (SADQ-C)¹				
NAME _____		AGE _____		No. _____
DATE: _____				
Please recall a typical period of heavy drinking in the last 6 months.				
When was this? Month: _____ Year: _____				
Please answer all the following questions about your drinking by circling your most appropriate response.				
During that period of heavy drinking				
1. The day after drinking alcohol, I woke up feeling sweaty.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
2. The day after drinking alcohol, my hands shook first thing in the morning.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
3. The day after drinking alcohol, my whole body shook violently first thing in the morning if I didn't have a drink.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
4. The day after drinking alcohol, I woke up absolutely drenched in sweat.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
5. The day after drinking alcohol, I dread waking up in the morning.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
6. The day after drinking alcohol, I was frightened of meeting people first thing in the morning.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
7. The day after drinking alcohol, I felt at the edge of despair when I awoke.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
8. The day after drinking alcohol, I felt very frightened when I awoke.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
9. The day after drinking alcohol, I liked to have an alcoholic drink in the morning.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
10. The day after drinking alcohol, I always gulped my first few alcoholic drinks down as quickly as possible.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	
11. The day after drinking alcohol, I drank more alcohol to get rid of the shakes.				
ALMOST NEVER	SOMETIMES	OFTEN	NEARLY ALWAYS	

Appendix 4: SADO –C SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE (TAMIL VERSION)

SEVERITY OF ALCOHOL DEPENDENCE QUESTIONNAIRE			
பெயர் :	வயது :	தேதி :	
கடந்த 6 மாதங்களில் மிக அதிகமாக அது அருந்தியதை நினைவு கூறவும்.			
எப்பொழுது? மாதம் : வருடம் :			
உங்களின் குடிப்பழக்கம் குறித்த பின்வரும் கேள்விகளுக்கு உங்கள் பதில்களை வட்டமிட்டு காட்டவும்.			
மிக அதிகமாக மது அருந்தும் காலங்களில் :			
1	மது அருந்திய அடுத்த நாள் நான் எழுந்திருக்கும் போது அதிகமாக வீயர்ஸையை உண்கிறேன்.		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		
2	மது அருந்திய அடுத்த நாள் காலை எழுந்தவுடன் மன கைகள் நடுங்குவதை உண்கிறேன்.		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		
3	மது அருந்திய அடுத்த நாள் மது அருந்தவில்லை எனில் எனது உடல் மிகத் தீவிரமாக நடுங்குவதை உண்கிறேன்.		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		
4	மது அருந்திய அடுத்த நாள் நான் எழும் போது முழுவதும் வீயர்ஸையில் நனைந்திருக்கிறேன்.		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		
5	மது அருந்திய அடுத்த நாள் காலையில் பெரும் பயத்துடன் எழுந்திருக்கிறேன்		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		
6	மது அருந்திய அடுத்த நாள் காலையில் பிறரை சந்திக்கும் போது பயப்படுகிறேன்		
	எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்		

7	மது அருந்திய அடுத்த நாள் காலையில் எழும் போது நம்பிக்கை இல்லாதது போல் உணர்கிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
8	மது அருந்திய அடுத்த நாள் காலையில் எழுந்த பின் பயத்தை உணர்கிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
9	மது அருந்திய அடுத்த நாள் மீண்டும் காலையில் மது அருந்த விரும்புகிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
10	மது அருந்திய அடுத்த நாள் மீண்டும் மது அருந்தும் போது முதலில் சீறிது மதுவை மிக வேகமாக விழுங்குகிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
11	மது அருந்திய அடுத்த நாள் நடுக்கத்தைத் குறைப்பதற்காக அதிக அளவு அருந்துகிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
12	மது அருந்திய அடுத்த நாள் காலையில் எழும் போது மதுவின் மீது ஆர்வம் அதிகமாகிறது	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
13	நான் ஒரு நாளைக்கு ஒரு குவார்ட்டர் சாராயம் (1 ஓயின் அல்லது 7 பி) அதற்கு மேல் குடிக்கிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்
14	நான் ஒரு நாளைக்கு அரை பாட்டில் சாராயம் (2 பாட்டில் ஓயின் அல்லது 15 பி) அதற்கு மேல் குடிக்கிறேன்	எப்போதும் இல்லை	எப்போதாவது	அடிக்கடி	எப்போதும்

- 15 நான் ஒரு நாளைக்கு ஒரு பாட்டில் சராயம் (4 பாட்டில் ஒயின் அல்லது 30 பீர்) அதற்கு மேல் குடிக்கிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

- 16 நான் ஒரு நாளைக்கு 2 பாட்டில் சராயம் (8 பாட்டில் ஒயின் அல்லது 60 பீர்) அதற்கு மேல் குடிக்கிறேன்

எப்போதும் இல்லை எப்போதாவது அடிக்கடி எப்போதும்

பின் வரும் நிகழ்வுகளை கற்பனை செய்யவும்

- 1 நீங்கள் சில ஸாரங்கள் மது அருந்துவதை முற்றிலும் நிறுத்தி விடலாம்
- 2 அதற்கு அடுத்த 2 நாட்கள் மிக அதிகமாக மது அருந்துகிறீர்கள்
- 3 இரண்டு நாட்கள் கழந்தபின் காலையில் எப்படி உணர்வீர்கள்?

- 17 எனக்கு விபரங்க ஆரம்பிக்கும் ஒரு போதும் இல்லை கொஞ்சம் மீதமாக மிக அதிகமாக

- 18 எனது கைகள் நடுங்கும் ஒரு போதும் இல்லை கொஞ்சம் மீதமாக மிக அதிகமாக

- 19 எனது உடல் நடுங்கும் ஒரு போதும் இல்லை கொஞ்சம் மீதமாக மிக அதிகமாக

- 20 எனக்கு மதுவின் மீது தீவரம் அதிகரிக்கும் ஒரு போதும் இல்லை கொஞ்சம் மீதமாக மிக அதிகமாக

APPENDIX 5: URICA –ENGLISH VERSION

University of Rhode Island
Change Assessment Scale (URICA) :
DELTA Project Reduced Drinking Version

Client ID# _____
Date: ____/____/____
Assessment Point: _____

EACH STATEMENT BELOW DESCRIBES A HOW A PERSON MIGHT FEEL WHEN APPROACHING PROBLEMS RELATED TO DRINKING IN THEIR LIVES. PLEASE INDICATE HOW MUCH YOU TEND TO AGREE OR DISAGREE WITH EACH STATEMENT. IN EACH CASE, MAKE YOUR CHOICE IN TERMS OF HOW YOU FEEL RIGHT NOW. NOT WHAT YOU HAVE FELT IN THE PAST OR WOULD LIKE TO FEEL.

THERE ARE FIVE POSSIBLE RESPONSES TO EACH OF THE ITEMS:

- 1=Strongly Disagree
- 2=Disagree
- 3=Undecided
- 4=Agree
- 5=Strongly Agree

INDICATE THE NUMBER THAT BEST DESCRIBES HOW MUCH YOU AGREE OR DISAGREE WITH EACH STATEMENT.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1) It doesn't make much sense for me to consider changing my drinking.	1	2	3	4	5
2) I've been thinking that I might want to change something about my drinking.	1	2	3	4	5
3) At times my drinking causes problems and I'm determined to change.	1	2	3	4	5
4) It is frustrating, but I feel I might be having a recurrence of a drinking problem I thought I had resolved.	1	2	3	4	5
5) Trying to change my drinking is pretty much a waste of time for me.	1	2	3	4	5
6) I guess I have faults, but there's nothing that I really need to change about my drinking.	1	2	3	4	5
7) I thought once I had resolved my problem drinking I would be free of it, but sometimes I still find myself struggling with it.	1	2	3	4	5
8) I may have a problem with drinking and I think I should work on it.	1	2	3	4	5
9) I am really working hard to change my drinking.	1	2	3	4	5
10) I hope that someone will have some good advice for me about my drinking.	1	2	3	4	5

11) Anyone can talk about changing the way they drink; I'm actually going to do something about it.	1	2	3	4	5
12) After all I had done to try and change my problem drinking, every now and then it comes back to haunt me.	1	2	3	4	5

APPENDIX 6:URICA (TAMIL VERSION)

URICA

ஒவ்வொரு கேள்விக்கும் கீழே உள்ள ஐந்து பதில்களில் ஒன்றை வட்டமிடவும்

- 1 இந்த மையத்திற்கு வருவதற்கு உண்டான காரணம் எதுவும் எனக்கு இல்லாததால், இரண்டு தங்கி இருக்கும் நேரம் வீணானது

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 2 எனக்கு மனரீதியாகவும் உணர்வு ரீதியாகவும் மீண்டும் பிரச்சினைகள் உண்டாகாமல் தடுப்பதற்காக இந்த மையத்தில் இருப்பதாக கருதுகிறேன்.

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 3 என்னிடம் தவறுகள் இருக்கலாம் என்று கருதினாலும் நான் மாற வேண்டியது ஒன்றுமில்லை.

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 4 நான் மாறுவதற்காக மிக கடினமாக முயற்சி செய்கிறேன்

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 5 எனக்கு மனரீதியாகவும் உணர்வு ரீதியாகவும் பிரச்சினைகள் உண்டு என்றும் அதைப்பற்றி முழு ஆய்வு தேவை என்றும் உணர்கிறேன்

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 6 நான் என்னை உணர்வதற்கு துணை செய்யும் என்று நம்புகிறேன்

1 தீவிர உடன்பாட்டில் இல்லை	2 உடன்பாடு இல்லை
3 முடிவு செய்ய முடியவில்லை	4 உடன்படுகிறேன்
5 முழுமையாக உடன்படுகிறேன்	

- 7 நான் மனரீதியாகவும் உணர்வு ரீதியாகவும் இருக்கும் பிரச்சினைகளுக்கு தீர்வு காணும் போது அப்பிரச்சினையில் இருந்து விடுபட்டு விட்டதாக கருதினாலும், அந்த பிரச்சினையிலேயே மீண்டும் சிக்கி தவிக்கிறேன்
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |
- 8 இந்த மையம் எனக்கு உதவி செய்யும் என்று உணருகிறேன்
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |
- 9 இந்த பிரச்சினைகளின் ஒரு பகுதிக்கு நான் காரணமாக இருக்கலாம் என்றாலும், நான் அப்படி சிந்திக்கவில்லை.
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |
- 10 மாறுவதைப் பற்றி யாரும் பேசுவது சுலபம் ஆயினும் மாற வேண்டும் என்பதற்காக சிலவற்றை நான் செய்து கொண்டு இருக்கிறேன்
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |
- 11 மனரீதியாகவும் உணர்வு ரீதியாகவும் ஏற்பட்ட பிரச்சினைகளில் இருந்து விடுபட்டதாக கருதிய நேரத்தில் அந்தப் பிரச்சினைகளில் மீண்டும் சிக்கி விடுவேன் என்று நினைக்கும் போது வாழ்க்கை மீது வெறுப்பு தோன்றுகிறது.
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |
- 12 மனரீதியாகவும் உணர்வு ரீதியாகவும் ஏற்படும் பிரச்சினைகளில் இருந்து விடுபட நான் மிகவும் தீவிரமாக முயற்சி செய்கிறேன்.
- | | | | |
|---|--------------------------|---|----------------|
| 1 | தீவிர உடன்பாட்டில் இல்லை | 2 | உடன்பாடு இல்லை |
| 3 | முடிவு செய்ய முடியவில்லை | 4 | உடன்படுகிறேன் |
| 5 | முழுமையாக உடன்படுகிறேன் | | |

APPENDIX 7 : INFORMED CONSENT

<p>Study Volunteer ID: Study Volunteer Name:</p>	<p>Version 2.3.2, Effective: 20th August, 2013</p>
<p>PSG Institute of Medical Science and Research, Coimbatore Institutional Human Ethics Committee INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS</p>	
<p>I Dr.Pranesh R.R. am / are carrying out a study on the topic: Continuing care through tele-counseling in alcohol de-addiction program – A randomized controlled study as part of my / our research project being carried out under the Department of Psychiatry My research guide is: Dr.Raghuathan G.,Professor and HOD</p> <p>The objectives of this study are: Primary Objective: To prospectively study whether brief counseling over mobile phone would increase the abstinence rate and reduce the drinking frequency when compared to 'treatment as usual' over one year period Secondary Objective: To find out the components of de-addiction treatment those are associated with abstinence. Sample size: 72 patients. Location: PSGIMSR, Coimbatore.</p> <p>We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study.</p> <p>Data collected will be stored for a period of five years. We will / will not use the data as part of another study. If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, you have the right to withdraw from the interview / study at anytime. You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will NOT be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings – including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.</p>	
<p>Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I also hereby agree to communicate to me and give counseling through telephone/mobile phone with regards to this research study on alcohol de-addiction. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).</p> <p>Signature / Left thumb impression of the Study Volunteer / Legal Representative:</p> <p>Signature of the interviewer with date: _____ Witness: _____</p>	

APPENDIX 8 :INFORMED CONSENT (TAMIL VERSION)

ஒப்புதல் படிவம்

தேதி:

டாக்டர். ப்ரவேஷ். ஆர். ஆர். ஆரிய நான். பி.எஸ்.ஜி மருத்துவக் கல்லூரியின் மனநல மருத்துவத் துறையின் கீழ், மது அடிமைத் தனத்தில் இருந்து விடுபட தொலைபேசி மூலம் மருத்துவ ஆலோசனை வழங்குதல் தொடர்பான மருத்துவ ஆராய்ச்சி மேற்கொள்ள உள்ளேன்.

ஏன் ஆய்வு வழிகாட்டி : டாக்டர். கோ. ரகுதாமன், பேராசிரியர் மற்றும் துறைத் தலைவர்

ஆய்வு மேற்கொள்வதற்கான அடிப்படை :

பெருகி வரும் மதுபழக்கமும், மதுவிற்கு அடிமையான அனைவரும் மருத்துவமனைக்கு சென்று ஆலோசனை பெற இயலாத நிலைமை

ஆய்வின் நோக்கம் :

மது அடிமைத்தனத்தில் இருந்து விடுபட சிகிச்சை அளிப்பதில் மருத்துவ சிகிச்சையும் மருத்துவ ஆலோசனையும் முக்கிய அம்சமாகும். தொலைபேசி, கைபேசி ஆகியவற்றின் எண்ணிக்கை நாளுக்கு நாள் அதிகமாகும் சூழ்நிலையில், மாறிவரும் தொழில் நுட்ப அறிவு கொண்டு மது அடிமைத்தனத்தை நீக்க மருத்துவ சிகிச்சையோடு தொடர் ஆலோசனை வழங்குதல் மூலம் தேரில் ஆலோசனை வழங்குவதைக் காட்டிலும் கைபேசி மூலம் ஆலோசனை வழங்கும் போது எதிர்பார்த்த பரன் கிடைக்க வாய்ப்புகள் அதிகமாகுமா என்று கண்டறிதல்.

ஆய்வு மேற்கொள்ளும் இடம் :

பி.எஸ்.ஜி மருத்துவமனை, கோயம்புத்தூர்

ஆய்வின் பலன்கள் :

மது அருந்துவதால் ஏற்படும் தீய விளைவுகளையும் மது அருந்துவதை நிறுத்துவதால் ஏற்படும் நன்மைகளையும் தொடர்த்து சொல்வதன் மூலம் மதுவிற்கு அடிமை ஆனவர்களின் எண்ணிக்கையை குறைத்து அவர்களின் உடல் மற்றும் உள்மனம் சீரமைப்பு ஆவதற்கு உதவுதல்

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் ஐந்து வருடங்கள் பாதுகாக்கப்படும். இவை வேறு எந்த ஆய்விற்கும் பயன்படுத்தப்பட மாட்டாது. எந்த நிலையிலும் உங்களைப் பற்றிய தகவல்கள் யாருக்கும் தெரிவிக்கப்படமாட்டாது. அவை இரகசியமாக வைக்கப்படும்.

இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் எந்த விதமான பரனும் உங்களுக்குக் கிடைக்காது.

எந்த தேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு.

ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில் எந்த வத மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும். மேலும் இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம். இதில் எந்த விதக் கட்டாயமும் இல்லை. நீங்கள் விரும்பப்பட்டால் இந்த ஆய்வின் முடிவுகள் உங்களுக்குத் தெரியப்படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம் :

தேதி :

ஆய்வுக்குட்படுவரின் ஒப்புதல் :

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்நோக்கத்தை பற்றி தெளிவாகவும், விளக்கமாகவும் தெரியப்படுத்தப்பட்டுள்ளேன். இந்த ஆராய்ச்சியில் பங்கு கொள்ளவும், இந்த ஆராய்ச்சியின் மருத்துவ ரீதியான குறிப்புகளை வரும் காலத்திலும் உபயோகப்படுத்தித் கொள்ளவும் முழு மனதுடன் சம்மதிக்கிறேன். ஆராய்ச்சிக்காக மருத்துவர் என்னிடம் தொலைபேசி, கைபேசி மூலம் பேசுவதற்கும் ஆலோசனை வழங்குவதற்கும் நான் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுவரின் பெயர், முகவரி :

கையொப்பம் :

தேதி :